Operator's Manual AVL COMPACT 3

pH / Bloodgas Analyzer

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- Important Information! - Important Information! -

This **Operator's Manual** contains important **warnings and safety** instructions to be observed by the user.

This instrument is only intended for one area of application which is described in the instructions. The most important prerequisites for application, operation and safety, are explained to ensure smooth operation. No warranty or liability claims will be covered if the instrument is applied in areas other than those described or if the necessary prerequisites and safety measures are not observed.

The instrument is only to be operated by qualified personnel capable of observing these prerequisites.

Only accessories and supplies either delivered by or approved by AVL are to be used with the instrument.

Due to this instrument operating principle, analytical accuracy not only depends on correct operation and function, but also upon a variety of external influences beyond manufacturers control. Therefore the test results from this instrument must be carefully examined by expert, before further measures are taken based on the analytical results.

Instrument adjustment and maintenance with removed covers and connected power mains, are only to be performed by a qualified technician who is aware of the dangers involved.

Instrument repairs are only to be performed by the manufacturer or qualified service personnel.

Explanation:



This symbol is located on the inside of the instrument:

"Refer to the Operator's Manual / Service Manuals".



Symbol for instrument type B:

An instrument of the B-type falls under safety categories I, II or III, or has an internal power supply, providing the required insulation against discharge current and reliable ground connections.

- Important Information! - Important Information! -

Operating Safety Information -

- The instrument falls under Safety Category I.
- The instrument belongs to Type B.
- The instrument is designed as a conventional device (of closed, not waterproof type).
- Do not operate the instrument in an explosive environment or in the vicinity of explosive anesthetic mixtures containing oxygen or nitrous oxide.
- The instrument is suitable for continous operation.

CAUTION:

- The mains plug may be plugged only into a grounded socket. When using an extension cord, make sure it is properly grounded.
- Any rupture of the ground lead inside or outside the instrument or a loose ground connection can render hazardous operation of the instrument. Intentional disconnection of the grounding is not permitted.
- While changing the fuses, make sure that the fuses used, are of the specified type and rating in every case. Never use repaired fuses or short-circuit the fuse holders.

Operating Safety Information -

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Method Sheet

Intended Use

The AVL COMPACT 3 pH/Blood Gas Analyzer is intended to be used for the measurement of pH, PCO₂ and PO₂ in samples of whole blood.

Clinical Significance¹

рΗ

The pH value of the blood, serum or plasma, may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH-values are generally classified as:

- a) primary bicarbonate deficit metabolic acidosis
- b) primary bicarbonate excess metabolic alkalosis
- c) primary hypoventilation respiratory acidosis
- d) primary hyperventilation respiratory alkalosis

An increase in blood, serum or plasma pH (alkalemia) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO₂ due to hyperventilation.

A decreased pH value (acidemia) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H⁺-ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic; as the result of obstructive or restrictive respiratory diseases.

PCO₂

The PCO_2 value of arterial blood is used to assess how well the body eliminates carbon dioxide in relation to the metabolic rate of CO_2 production. A PCO_2 below the normal range is termed respiratory alkalosis and indicates hypocapnia, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial PCO_2 above the normal range is termed respiratory acidosis and indicates hypercapnia, a sign of hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

¹ Teitz, Norbert W., Ed., Clinical Guide to Laboratory Tests, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p.436.

 PO_2

The PO_2 value of arterial blood has become the primary tool for the evaluation of arterial oxygenation status. Values below the normal arterial PO_2 (arterial hypoxemia) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decreased cardiac output, increased oxygen demand, anatomical heart defect, low inspired O_2 content). Generally, PO_2 levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg PO_2 provides a 97% saturation level, and a level greater than 100% cannot be achieved.

Principles of Procedure

There are 4 electrodes used in the AVL COMPACT 3 pH/Blood Gas Analyzer; a pH Electrode, a pH reference electrode, a PCO₂ Electrode and a PO₂ Electrode.

pH Measurement

pH of a solution is defined by the negative logarithm of the activity of Hydrogen ions, and described by the equation:

$$pH = -log[H^+]$$

A single measurement of the electric potential of a solution, under proper conditions, can be directly related to the concentration of Hydrogen ions. In pH measurement systems, a bulb of special glass is filled with a conductive buffer solution of known pH in contact with the measuring instrument through a conductive, metallic electrode. When this special electrode is immersed in an aqueous solution, water molecules diffuse into the structure of the glass and form a hydrated layer. A potential difference develops between the solution inside the glass electrode and the solution being measured for [H⁺]. The magnitude of this difference depends solely on the concentration of Hydrogen ions in the solution. This difference is measured by combining the glass electrode with standard, calomel, reference electrode and measuring the voltage of the system.

Calibration of the system is accomplished by using buffer solutions with known pH values traceable to buffers with values assigned by the National Institute of Standard Technology. The pH of the unknown solution is compared to known buffer solution by electric potential measurement by the instrument using specially designed electrodes arranged as a special type of concentration cell which is described by a modification of the Nernst equation:

$$E = E_0 + \frac{RT}{nF} \ln a_{H^+}(mv)$$

where: E_0 = standard potential in mV

 $R = gas constant (8.3143 joule \times K^{-1} \times mol^{-1})$

T = temperature degrees Kelvin (310.15 °K = 37 °C)

n = number of electrons in electrochemical reaction

F = value of the Faraday constant (96487 coulomb × mol⁻¹)

 a_{H}^{+} = Hydrogen ion activity

pH Electrode

The pH Electrode consists of a single glass tube with a special pH-sensitive glass membrane at its tip. Hydrogen ions in a sample at the time diffuse into the hydrated glass layer and generate an electric potential. This potential is conducted through a gelled buffer solution of constant pH to the instrument through an AgCl coated silver pin immersed in the buffer and connected to the instrument with a cable and plug. The electrical circuit is completed through the sample path to the pH Reference Electrode and a second instrument input. The potential difference (measuring voltage) is amplified for easier processing. With the help of a calibration curve determined by calibration points near 7.38 and 6.84, and by using the measured voltage of the sample, the ion concentration of the sample is determined and converted to pH for display.

pH Reference Electrode

The pH Reference Electrode consists of a glass tube filled with calomel paste (mercurous chloride) in contact with mercury surrounding a platinum wire. This mixture is kept moist with a cotton plug at the end of the glass tube immersed in a solution of potassium chloride (KCl) and contained in a disposable housing. The mixture of metals in the electrode generates a constant voltage. A porous membrane at the tip of the housing provides a liquid junction with the sample and the KCl solution serves as a salt bridge, establishing contact between the instrument, calomel element and pH Electrode through the sample in contact with the KCl at the housing tip.

PCO₂

The PCO₂ Electrode consists of a pH-glass electrode and an Ag/AgCl reference electrode that forms the outer part that is surrounded by a common electrolyte solution. They are separated from the sample or calibration gas by a CO₂ permeable but not ion-permeable membrane. Carbon dioxide diffuses in both directions through the membrane until an equilibrium is established between the CO₂ partial pressure of the sample and the CO₂ partial pressure of the very thin electrolyte layer between the membrane and the glass electrode. At this time, the pH-value of the electrolyte solution has been changed by a chemical reaction, which occurs as carbon dioxide gas dissolves in the electrolyte and produces hydrogen ions.

$$CO_2 + H_2O \Leftrightarrow H_2CO_3 \Leftrightarrow H^+ + HCO_3^-$$

This pH change is measured and amplified and is indicated as the PCO_2 value. Methodology is a modification of the galvanometric pH measurement.

 PO_2

The PO_2 Electrode consists of a glass electrode body containing the cathode (4 platinum wires) and a silver anode, an electrode housing containing an O_2 -permeable membrane and inner electrolyte that enables the chemical reaction and transports the charges. The O_2 diffuses through the membrane, depending on the O_2 partial pressure of the sample, and continuously replaces the O_2

molecules of the electrolyte layer consumed during the cathode reaction. A very small constant current, representing the oxygen partial pressure PO_2 of the samples passes through the electrode.

Methodology is polarographic. At the cathode, oxygen diffused through the membrane is reduced through a series of reactions producing current between the cathode and anode proportionate to the oxygen tension:

$$O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$$

Cathode Reaction

$$4\text{NaCl} + 4\text{OH}^- \rightarrow 4\text{NaOH} + 4\text{Cl}^-$$

Electrolyte Reaction

$$4Ag \rightarrow 4Ag^{\scriptscriptstyle +} + 4e^{\scriptscriptstyle -} \rightarrow 4Cl^{\scriptscriptstyle -} + 4Ag^{\scriptscriptstyle +} \rightarrow 4AgCl + 4e^{\scriptscriptstyle -} \qquad \text{Anode Reaction}$$

The electrons in the initial reaction are supplied by a constant voltage of -0.7 V. In this series of equations, it is apparent that for the reduction of each oxygen molecule, 4 electrons are consumed.

Reagents and Accessories

Buffer Type 1 (pH=7.383)

Order number: BP0136

Use: For calibration of pH in AVL pH/Blood Gas instruments

Contents: 1 package contains 3 ready to use containers with 90 mL

each

Composition: Potassium dihydrogen phosphate, 13.619 mmol/L

Disodium hydrogen phosphate, 53.14 mmol/L

Lithium carbonate, 0.25 mmol/L

Additives: Germicides

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each container

label

Buffer Type 2 (pH=6.841)

Order number: BP0137

Use: For calibration of pH in AVL pH/Blood Gas instruments

Contents: 1 package contains 3 ready to use containers with 90 mL

each

Composition: Potassium dihydrogen phosphate, 25.0 mmol/L

Disodium hydrogen phosphate, 25.0 mmol/L

Additives: Germicides

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each container

label

pH Reference Solution

Order number: BP0134

Use: For calibration of pH in AVL pH/Blood Gas instruments

Contents: 1 package contains 3 ready to use containers with 90 mL

each

Composition: Potassium chloride, 600 mmol/L

Additives: Germicides

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each container

label

Rinse Order number: BP1890

Use: For calibration of pH in AVL pH/Blood Gas instruments

Contents: 1 package contains 6 ready to use containers with 430 mL

each

Composition: Dehydran 241,0.065 g/L

Dehydol 100, 0.0065 g/L

Additives: Germicides

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each package

Cleaning Solution Order number: BP1889

Use: For the daily cleaning of the AVL COMPACT 3 measuring

system

Contents: 1 package contains 3 ready to use containers with 90 mL each

Composition: Sodium bicarbonate, 4.1 g/L

Sodium chloride, 2.5 g/L Antarox BL344, 1.0 g/L 2-phenylethanol, 0.1 g/L Hyamine 1622, 0.05 g/L

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each package

Deproteinizer Order number: BP0521

Use: For periodic cleaning of the measuring system after lipemic

samples or as required for decontamination.

Contents: Each dispensing bottle contains 100 mL of solution.

Composition: Sodium hypochlorite, 16.0 g/L

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each container

label.

PCO₂ Filling Solution

Order number: BP1286

Use: Electrolyte solution used in remembranable *PCO*₂

Electrodes.

Contents: Each dispensing bottle contains 100 mL of solution.

Composition: Potassium chloride, 25.0 mmol/L

Sodium bicarbonate, 10.0 mmol/L

Additives: Germicides

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each container

label.

PO₂ Filling Solution

Order number: **BP1414**

Use: Electrolyte solution used in remembranable PO_2 Electrodes.

Contents: Each dispensing bottle contains 100 mL of solution.

Composition: Ethylene glycol: 1000 g/L

Regent grade water: 100 g/L

Disodium hydrogen phosphate: 5.34 g/L Potassium dihydrogen phosphate: 2.45 g/L

Sodium chloride: 0.58 g/L

Additives: Germicides

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each container

label.

Calibration Gas 1

Order number: HL0020

Use: For the calibration of PO_2 and PCO_2 in the AVL COMPACT 3

pH/Blood Gas Analyzer

Contents: Each disposable cylinder contains 3.15 L at 2200 PSI at 70 °F

(150 bar at 21°C)

Composition: Oxygen: $20.0\% \pm 0.03\%$

Carbon Dioxide: $5.5\% \pm 0.03\%$

Nitrogen: balance

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each container

label

Calibration Gas 2 Order number: HL0021

Use: For the calibration of PO_2 and PCO_2 in the AVL COMPACT

3 pH/Blood Gas Analyzer

Contents: Each disposable cylinder contains 3.15 L at 2200 PSI at

70 °F (150 bar at 21°C)

Composition: Carbon Dioxide: $10.0\% \pm 0.03\%$

Nitrogen: balance

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are printed on each container

label

Capillary Tubes Order number: MG0002

Use: For collection and transport of capillary blood specimens for

pH/Blood Gas and Electrolyte analysis. Not to be used for

collection of samples for analysis of Lithium

Contents: Each package contains 250 capillary tubes

Composition: Each tube is coated to contain 6 I.U. Sodium heparin and

9 I.U. Lithium heparin per 100 µL tube volume. Each tube has

a minimum volume of 115µL

Storage: Temperature: 5 - 30 °C (41 - 86 °F)

Stability: Expiration date and lot number are labeled on the bottom of

each container

Precautions: Use of calibration solutions or electrodes not manufactured for AVL

could void the warranty.

A waste container is provided. Once used, the waste container holds human body fluids which may be potentially infectious; handle with

appropriate care to avoid skin contact or ingestion.

For in-vitro diagnostic use.

Specimen Collection and Handling

Safety

Universal precautions must be observed when collecting blood specimens. It is recommended that all blood specimens be handled as if capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV), or other bloodborne pathogens. Proper blood collection techniques must be followed in order to minimize risk to the laboratory staff, and gloves should be worn. Please refer to NCCLS document M29-T2, Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue - Second Edition; Tentative Guideline for further information on safe handling of these specimens.

Sample Requirements

Refer to NCCLS document H11-A2, *Percutaneous Collection of Arterial Blood for Laboratory Analysis - Second Edition*; Approved Standard, May 1992, for detailed information of sample collection, storage and handling.

Blood sampling for analysis must be performed under proper medical supervision with details of collection, including sampling devices, site selection, sample handling, documentation and specific procedures used approved by the personnel responsible.

Anticoagulants

Lithium heparin, Sodium heparin or balanced heparin salts (as often used for samples taken also for electrolyte analysis) are the only acceptable anticoagulants for blood gas analysis. Other anticoagulants such as EDTA, citrate, oxylate and fluoride have a significant effect on blood pH and should not be used. Lithium heparin should not be used for samples taken also for analysis of Lithium.

Sample Collection Devices

Syringes

If liquid heparin is used as an anticoagulant, collection devices should be no larger than the amount of blood required minimizing the effects of dilution of the blood by the anticoagulant solution. Although plastic syringes are commonly used for collection of blood specimens for blood gas analysis, there have been reports in the literature regarding the use of plastic syringes when PO_2 values higher than normal are expected. Particular attention should be paid to cooling blood samples in ice water, because of the CO_2 and oxygen solubility in some plastics. If blood specimens are expected to have very high PO_2 values, care should be taken to analyze the specimen as quickly as possible following collection to avoid the need for cooling.

Capillary Tubes

Capillary blood specimens should be collected using AVL capillary tubes, which have a minimum volume, filled, of 115 μ L and are ideally suited for use with the AVL COMPACT 3. The AVL capillary tubes for pH and blood gas analysis should not be used for samples taken for the analysis of Lithium.

Samples may be collected in capillary tubes after warming the area or otherwise stimulating it to promote arterial circulation before the puncture. The puncture should be made deeply enough to ensure a free and rapid flow of blood.

Do not use clay-capped capillary tubes as the rough, broken edge left when the capillary is cut may cause damage to the AVL COMPACT 3 fill port. Use only capillary tubes with fire-polished ends to prevent damage to the instrument. If a mixing flea is used, as required in some capillary tubes, take care to remove the flea prior to sample introduction to avoid damage to the AVL COMPACT 3.

Specimens collected in capillary tubes are stable at room temperature for up to 30 minutes after collection because of the rapid cooling of the sample accomplished during filling.

AVL Microsampler

Blood may be collected for analysis on the AVL COMPACT 3 with the AVL Microsampler to provide two filled capillary tubes which may be used for analysis on separate instruments for split-sampling, for CO-Oximetry measurement or for the analysis of electrolytes other than Lithium.

After collection, the AVL Microsampler should be capped and transported in a horizontal position to the instrument for analysis within 30 minutes, as with all specimens collected in capillary tubes.

Vacuum Tubes

Venous specimens collected in vacuum tubes containing Lithium or Sodium heparin may be used. Ensure that the tube is completely filled and that the sample is thoroughly mixed immediately after collection by gentle inversion. Blood gas values reported from venous specimens should be clearly identified as such to allow for correct interpretation.

Each laboratory should determine the acceptability of its own blood collection syringes and capillaries. Variations in these products exist between manufacturers, and at times, from lot to lot.

Handling and Storage of Samples

Please refer to NCCLS Document C27-A, Blood Gas Pre-Analytical Considerations: Specimen Collection, Calibration and Controls; Approved Guideline, April 1993 for a detailed discussion of guidelines for the collection of acceptable specimens, instrument calibration, and quality control in pH and blood gas analysis; including details of many potential sources of error which may cause inaccurate results.

Whole Blood

Arterial Specimens

Whole blood samples should be collected in a heparinized syringe, AVL Microsampler or capillary and analyzed as soon as possible after collection. Immediately after collection, check the syringe or other device for air bubbles and carefully expel any trapped bubbles, following the manufacturer's recommended procedure. Extreme caution should be used to avoid needle stick injury. Mix the specimen collected in a syringe thoroughly with anticoagulant by gentle inversion or by rolling the syringe between both hands. Properly identify the specimen, following usual procedures for such documentation. Place the syringe containing the specimen in an ice slurry. Blood gases and pH will change if the specimen remains at room temperature in a syringe for more than 5 minutes due to cellular metabolism. PO₂ changes due to oxygen consumption may be influenced by several factors, including white blood cell count, reticulocyte count, storage temperature and initial PO₂ value. At a storage temperature of 1 to 5 °C, the results obtained are valid up to 2 hours. Samples expected to have high white blood cell count, reticulocyte count, or high PO2 values initially should be analyzed as soon as possible after collection.

Errors in blood gas analysis on properly collected samples may result from improper mixing of the sample after collection and before measurement; contamination with room air resulting from failure to expel trapped bubbles after collection; and from metabolic changes in the sample.

Venous Specimens

Whole blood samples should be collected in a heparinized syringe, vacuum tube or capillary and analyzed as soon as possible after collection. The sample container should be filled as much as possible, leaving minimal residual air space. If storage for more than 5 minutes or up to 1 hour is required, the sample should be stored, cooled in an ice slurry (1 to 4 °C) prior to analysis.

Plasma

Plasma samples should be obtained by immediately centrifuging heparinized whole blood, separating the plasma from red cells and capping the sample tube. Analyze as soon as possible. If storage is required, the samples should be capped and refrigerated at 4 to 8 °C. Refrigerated samples should be allowed to warm to room temperature (15 to 32 °C / 50 to 90 °F) prior to analysis. Plasma samples more than one hour old must be centrifuged again to remove additional fibrin clots.

Serum

Serum samples should be obtained by collecting blood in an untreated blood collecting tube. The sample should stand for 30 minutes to allow the clot to form prior to centrifugation. After centrifugation, remove the serum from the clot, and cap or seal the sample tube. If storage is required, the sample should be stored, tightly capped, under refrigeration at 4 to 8 °C (39 to 46 °F), and allowed to return to room temperature, 15 to 32 °C (59 to 90 °F), prior to analysis.

Each laboratory should determine the acceptability of its own blood collection syringes, capillaries and tubes and the serum or plasma separation products. Variations in these products exist between manufacturers, and at times, from lot to lot.

Materials Needed

Reagents

Description	Part Number
pH Buffer Type 1	BP0136
pH Buffer Type 2	BP0137
pH Reference Solution	BP0134
Rinse	BP1890
Cleaning Solution	BP1887
Deproteinizer	BP0521
Calibration Gas 1	HL0020
Calibration Gas 2	HL0021
Printer Paper	HP0070

The AVL COMPACT 3 pH/Blood Gas Analyzer automatically processes the sample through the necessary steps, then prints and displays the results. For details of this operation, please refer to the Operator's Manual.

Test Conditions

Sample Size $50 \mu L$, capillary

100 μL, syringe

 $25~\mu L$, microsample mode

Sample Type whole blood

Sample Application syringe, capillary or AVL Microsampler

Ambient Temperature

15 - 32° C (59 - 89.6° F)

Relative Humidity 20% to 90% (non-condensing)

Type of Measurement

pH, PCO₂ galvenometric PO₂ polarographic

Measured Values

Parameter	Range	Display Resolution
pН	6.0 to 8.0 pH units	0.001 pH units
PCO ₂	0 to 200 mmHg	0.1 mmHg
	0.5 - 26.7 kPa	0.01 kPa
PO ₂	-10 to 742 mmHg	0.1 mmHg
	-1.33 to 98.7 kPa	0.01 kPa
Barometric Pressure	300 to 800 mmHg	0.1 mmHg
	0.0 to 106.0 kPa	0.01 kPa

Input Values

Parameter	Range	Display Resolution
Patient temperature, T	14.0 to 44.0 °C	0.1 °C
	57.1 to 111.2 °F	0.1 °F
Total Hemoglobin, tHb	1 to 26 g/dL	0.1 g/dL
	10 to 260 g/L	1.0 g/L
	0.7 to 16.1 mmol/L	0.01 mmol/L
Hemoglobin type	adult or fetal	
P50 adult	15 to 40 mmHg	0.1 mmHg
	2.0 to 5.33 kPa	0.01 kPa
P50 fetal	10 to 40 mmHg	0.1 mmHg
	1.34 to 5.33 kPa	0.01 kPa
Respiratory Quotient, RQ	0.71 to 1.99	0.01
Fraction of Inspired Oxygen FIO ₂	0.11 to 0.99	0.01
Patient number	0 to 999999999	
Patient age	0 to 99 years	1 year
Patient sex	male or female	

Calculated Values

Parameter		Range	Display Resolution
Actual Bicarbonate	HCO ₃	1 to 100 mmol/L	0.1 mmol/L
Base Excess,	BE	-40 to +40 mmol/L	0.1 mmol/L
Base Excess ecf,	BE _{ecf}	-40 to +40 mmol/L	0.1 mmol/L
Base Excess at actual oxygen saturation	BE _{act}	-40 to +40 mmol/L	0.1 mmol/L
Total CO ₂ ,	ctCO ₂	1 to 100 mmol/L	0.1 mmol/L
Standard Bicarbonate,	HCO _{3 st}	1 to 100 mmol/L	0.1 mmol/L
Standard pH,	pH st	6.5 to 8.0	0.001 pH units
Hydrogen ion concentration	cH ⁺	10 to 1000 nmol/L	0.1 nmol/L
Functional Oxygen saturation,	SO_2	0 to 100 %	0.1%
Oxygen content,	ctO_2	0 to 56 mL/dL	0.1~mL/dL
Alveolar arterial oxygen partial pressure difference,	$AaDO_2$	0 to 742 mmHg	0.1 mmHg

Parameter		Range	Display Resolution
Standardized ionized Calcium (at Datalink with AVL 988-3)	niCa pH=7.4	0.1 6.0 mmol/L	0.1mmol/L
PO ₂ at patient temperature	PO ₂ ^t	0742 mmHg	0.1 mmol/L
PCO ₂ at patient temperature	PCO ₂ ^t	0200 mmHg	0.1 mmol/L
pH at patient temperature	pH ^t	68	0.1 mmol/L
Shunt	$\frac{\dot{Q}s}{\dot{Q}t}$	0 to 100 %	0.1%

Types of Calibration

The AVL COMPACT 3 automatically performs a one-point gas calibration with each sample measurement. In addition, the AVL COMPACT 3 automatically performs a one-point pH calibration based upon user programmed intervals; either fixed at every half hour or one hour intervals or flexible at 1, 2, or 3 hour intervals based on the drift of the pH Electrode. The programmed interval may vary from site to site depending on usage and regulatory requirements. A two-point main calibration can be programmed to occur automatically at intervals from 2 to 12 hours in normal operation if no analysis is in progress. Automatic calibration also occurs shortly after power-on or reset. A calibration cycle can also be manually initiated any time a sample measurement is not being performed.

Quality Control

At least once daily or according to local regulations, run solutions at three levels (low, normal, high) of a quality control solution with known pH, PCO_2 and PO_2 values. For further details, review the Quality Control Section of the Operator's Manual. The result obtained should fall within limits defined by the day to day variability of the system as measured in the user's laboratory. If the results fall outside the laboratory's acceptable limits, refer to the Troubleshooting Section of the Operator's Manual.

Reference Interval²

Laboratory normal ranges for arterial carbon dioxide tension, $PaCO_2$ and pH are well documented and widely accepted:

Parameter	Mean	± 2 SD
pН	7.40	7.35 - 7.45
PaCO ₂ (mmHg)	40	35 - 45

Arterial oxygen tension, PaO_2 is dependent upon the inspired oxygen tension, as well as various physiologic variables, and the administration of oxygen is common in the treatment of patients in need of blood gas analysis.

Hypoxemia is defined as an arterial PO_2 below an acceptable range while breathing room air, with about 21% oxygen, at sea level. Increasing altitudes above sea level will produce lower inspired oxygen tensions and therefore, lower arterial PO_2 values.

Below are listed acceptable arterial oxygen tensions at sea level, while breathing room air:

PaO₂

Adult and Child

Normal	97 mmHg
Acceptable range	> 80 mmHg
Hypoxemia	< 80 mmHg

Newborn

Acceptable range 40 - 70 mm Hg

Aged

Acceptable range	60 years old	> 80 mmHg
	70 years old	> 70 mmHg
	80 years old	> 60 mmHg
	90 years old	> 50 mmHg

Each laboratory should establish its own reference interval for pH, PCO₂ and PO₂ as performed on the AVL COMPACT 3 Analyzer and at their laboratory altitude.

² Shapiro BA, Harrison RA, Cane RD, Kozlowski-Templin R: Clinical Application of Blood Gases, 4th ed., (Chicago: Year Bood Medical Publishers, Inc.,1991) pp 79-83.

Specific Performance Characteristics

All performance data in this section was generated on AVL COMPACT pH/Blood Gas systems with default calibration frequencies: continuous 1 point gas calibration, 1 point pH calibration at 1, 2 or 3 hour intervals determined automatically by the instrument based on calibration drift, and complete 2 point calibration every 12 hours, and without any correlation factors. The operating environment during the collection of this data was typical, varying from 22 to 26 °C (70 to 80 °F).

Limitations

The performance characteristics are affected by the following sample considerations:

The preferred test liquid is whole, human blood for all parameters. It is necessary to tonometer blood to obtain values to evaluate accuracy of PO_2 and PCO_2 because patient samples must be considered to be unknown. Tonometry of blood introduces potential errors unrelated to the blood gas system being evaluated, including: accuracy of the gas values used, temperature control and thermostatting of the tonometer, humidification of the tonometry gases, duration of tonometry and transfer of the sample from the tonometer to the instrument for analysis.

pH of blood cannot be predicted in tonometry. All tonometered samples analyzed in these studies were analyzed in duplicate on an AVL 995 to establish correlation. Precision of PO_2 and PCO_2 measurement, as well as pH was evaluated over a 20 day period using 2 AVL COMPACT pH/Blood Gas Analyzers with 2 replicates per run and 2 runs per day using a commercially available solution of reduced bovine hemoglobin which has been demonstrated to be comparable to tonometered whole blood.³

Precision and accuracy of pH was evaluated using commercially available precision pH buffer solutions with values traceable to N.I.S.T. and precision of pH, PCO₂ and PO₂ was evaluated using aqueous control materials.

Reproducibility

Typical Within-Run (S_{wr}) and Total (S_{τ}) imprecision data was collected from 2 runs per day with 2 replicates per run on three AVL COMPACT pH/Blood Gas Analyzers over twenty days following the protocol of NCCLS document number EP5-T2.

Material: AVL CONFITEST III Aqueous pH/Blood Gas Control, Level 1

Parameter	n	Mean	Swr	S ⊤
pН	240	7.207	0.0020	0.0043
PCO_2	240	18.8	0.20	0.27
PO_2	240	148.7	0.92	1.72

³ Mahoney JJ, Wong RJ, Van Kessel AL: Reduced Bovine Hemoglobin Solution Evaluated for Use as a Blood Gas Quality-Control Material. Clin.Chem.39/5, 874-879 (1993).

Material: AVL CONFITEST III Aqueous pH/Blood Gas Control, Level 2

Parameter	n	Mean	Swr	Sт
рН	240	7.410	0.0017	0.0047
PCO_2	240	37.4	0.23	0.42
PO_2	240	110.9	0.93	1.38

Material: AVL CONFITEST III Aqueous pH/Blood Gas Control, Level 3

Parameter	n	Mean	Swr	ST
рН	240	7.630	0.0021	0.0051
PCO_2	240	63.4	0.34	0.50
PO_2	240	74.1	0.78	1.42

Material: AVL CONFITEST III Aqueous pH/Blood Gas Control, Level 4

Parameter	n	Mean	Swr	Sт
рН	240	7.406	0.0012	0.0045
PCO_2	240	44.3	0.25	0.29
PO_2	240	288.6	1.93	5.43

Material: RNA Medical QUALIDATA™ pH/Blood Gas Electrolyte Control Level 1

Parameter	n	Mean	Swr	Sт
рН	240	7.144	0.0016	0.0043
PCO_2	240	70.3	0.55	0.87
PO_2	240	72.3	0.70	1.13

Material: RNA Medical QUALIDATA™ pH/Blood Gas Electrolyte Control Level 2

Parameter	n	Mean	Swr	ST
рН	240	7.395	0.0016	0.0065
PCO_2	240	44.5	0.24	0.34
PO_2	240	110.8	0.89	1.54

Material: RNA Medical QUALIDATA™ pH/Blood Gas Electrolyte Control Level 3

Parameter	n	Mean	Swr	ST
рН	240	7.596	0.0013	0.0073
PCO_2	240	23.0	0.18	0.38
PO_2	240	150.3	0.93	1.59

Material: RNA Medical EQUIL™ Reduced Bovine Hemoglobin Blood Tonometry Material⁴

Level 1: 11.0% CO₂, 20.93% O₂, balance N₂

Parameter	n	Mean	Swr	S T
рН	240	7.178	0.0015	0.0087
PCO_2	240	74.2	0.58	1.08
PO_2	240	149.2	1.19	1.95

Level 2: : 5.13% CO₂, 7.80% O₂, balance N₂

Parameter	n	Mean	Swr	Sт
pН	240	7.422	0.0017	0.0047
PCO_2	240	34.6	0.28	0.41
PO_2	240	56.5	0.75	1.25

Level 2: : 1.50% CO₂, 2.91% O₂, balance N₂

Parameter	n	Mean	Swr	ST
рН	240	7.732	0.0016	0.0048
PCO_2	240	11.0	0.09	0.24
PO_2	240	20.5	0.49	0.46

 $^{^4}$ Aliquots of Reduced Bovine Hemoglobin material were tonometered at 37°C. For each level, two replicates were run in two runs on three AVL COMPACT 3 pH/Blood Gas Analyzers for twenty days.

Precision and Linearity

Precision and Linearity of pH on Phosphate Buffer Solution

Ampoules of precision pH buffer solutions, with values traceable to N.I.S.T., were analyzed in random order in sets of 10 measurements on each of 6 AVL COMPACT pH/Blood Gas Analyzers.

Precision

pH Value @ 37 °C	n	Mean	WRSD
6.841 ± 0.005	60	6.8409	0.0023
7.100 ± 0.005	60	7.0993	0.0025
7.383 ± 0.005	60	7.3823	0.0024
7.600 ± 0.005	60	7.5976	0.0019

Linearity

Number of pairs (n): 240

slope (m): 0.9974 ± 0.0010 y-intercept (b): 0.0179 ± 0.0073

correlation coefficient (r): 1.0000

Linearity of pH on Whole Blood

180 runs were made on two AVL COMPACT pH/Blood Gas Analyzers and on 1 AVL 995 after being tonometered to various concentrations of CO_2 and O_2 gas at 37°C.

Number of pairs (n): 180

slope (m): 0.9979 ± 0.0016 y-intercept (b): 0.0118 ± 0.0114

correlation coefficient (r): 0.9998

Precision and Recovery on Whole Blood

Whole blood was tonometered at 37°C to various levels of gravimetrically prepared gases with CO_2 and O_2 concentrations certified to \pm 0.03% absolute by the manufacturer. Expected and observed values for PCO_2 and PO_2 were corrected to 760 mmHg. For each tonometered level, 10 replicates were run on two AVL COMPACT pH/Blood Gas Analyzers:

PCO₂

Analyte	type	n	Expected	Observed	S_{wr}	% Recovery
1.00% CO ₂	syringe	20	7.1	5.9	0.06	90
	capillary	20	7.1	6.4	0.07	86
1.50% CO ₂	syringe	20	10.7	10.8	0.14	101
	capillary	20	10.7	10.6	0.23	99
2.97% CO ₂	syringe	20	19.5	19.2	0.16	98
	capillary	20	19.5	19.1	0.11	98
4.00% CO ₂	syringe	20	28.5	28.7	0.12	101
	capillary	20	28.5	28.2	0.19	99
6.00% CO ₂	syringe	20	42.8	42.8	0.22	100
	capillary	20	42.8	42.7	0.35	100
8.00% CO ₂	syringe	20	57.0	57.5	0.28	101
	capillary	20	57.0	57.0	0.60	100
10.00% CO ₂	syringe	20	71.3	72.1	0.52	101
	capillary	20	71.3	72.5	0.19	102
14.00% CO ₂	syringe	20	99.8	100.9	0.45	101
	capillary	20	99.8	100.7	0.63	101
18.00% CO ₂	syringe	20	128.3	131.1	0.89	102
	capillary	20	128.3	129.7	0.55	101

Linearity

Number of pairs (n): 180

slope (m): 1.0205 ± 0.0010 y-intercept (b): -0.7408 ± 0.0637

correlation coefficient (r): 0.9999

PO_2

Analyte	type	n	Expected	Observed	S_{wr}	% Recovery
2.93% O ₂	syringe	20	20.9	20.9	0.30	100
	capillary	20	20.9	20.8	0.43	99
4.00% O ₂	syringe	20	28.5	28.3	0.37	99
	capillary	20	28.5	28.0	0.23	98
8.00% O ₂	syringe	20	57.0	56.6	0.44	99
	capillary	20	57.0	56.7	0.39	99
13.97% O ₂	syringe	20	99.6	99.1	0.58	99
	capillary	20	99.6	99.6	0.46	100
16.00% O ₂	syringe	20	114.1	113.9	0.58	100
	capillary	20	114.1	115.2	0.84	101
$20.00\%~O_2$	syringe	20	142.6	144.2	1.16	101
	capillary	20	142.6	140.8	1.56	99
30.00% O ₂	syringe	20	213.9	213.2	0.72	100
	capillary	20	213.9	210.8	2.62	99
50.00% O ₂	syringe	20	356.5	352.6	2.13	99
	capillary	20	356.5	350.4	2.73	98
80.00% O ₂	syringe	20	570.4	565.3	5.97	99
	capillary	20	570.4	562.9	2.82	99

Linearity

Number of pairs (n): 180

slope (m): 0.9872 ± 0.0008 y-intercept (b): 0.7362 ± 0.1920

correlation coefficient (r): 0.9999

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual).

Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Model equation for regression statistics is: [results of AVL COMPACT 3 Analyzer] = slope(m) x [comparative method results] + intercept(b).

Correlation to Other Methods

Whole Blood

Specimens were collected for blood gas analysis by traditional operators of blood gas equipment. The specimens were analyzed on existing instrumentation operated and controlled by hospital procedures. If any specimen remained after the initial run on the hospital system, the remainder was then run on the AVL COMPACT. The results of the AVL COMPACT analysis follows:

Comparative Method: AVL 995, Blood Gas Analyzer

			Correlation		
Parameter	Slope	Intercept	Coefficient	Range	n
pH	0.9862	0.108	0.9920	6.96-7.63	141
normalized to pH=7.4		0.006			
PCO_2	0.9886	0.516	0.9967	18 - 90	141
PO_2	0.9712	3.453	0.9976	1.7 - 376	141

Precision of Measurement in Whole Blood

Following is the summary of the expected performance specifications for the Normal, Capillary, Mini sample and Micro sample modes.

	Measuring Range (mmHg)	SD
pН	6.000-8.000	≤ 0.005
PCO_2	0-40	0-0.8 mmHg
	40-200	0.8-3.0 mmHg
PO_2	0-143	≤1.2 mmHg
	143-742	1.2-15.0 mmHg

Precision on Whole Blood

The standard deviation for pH in whole blood is not easily specified, because the pH value in-vitro can either be controlled or kept constant. The following data was obtained through timed recording of the pH values, the curve was fitted with a straight line and the mean deviation from this line was calculated.

pH Standard Deviation (1 Syx)

pH 6.000-8.000 0.005

For PCO2 and PO2, whole blood was tonometered at 37°C to various levels of gravimetrically prepared gases with CO₂ and O₂ concentrations. Five measurements were obtained at each of 10 levels of gas and Mean and SD were calculated for each of the four sample modes available on the AVL COMPACT pH/Blood Gas Analyzer: Syringe, Capillary, Mini, and Micro Sample. Measurement was also performed on the AVL OMNI Analyzer.

PCO2-Measurements

	Syr	inge	Сар	illary	Mi Sam			icro nple	TO	ΓAL
Target	\overline{X}	1SD	\overline{X}	1SD	\overline{X}	1SD	\overline{x}	1SD	\overline{X}	1SD
17.8	18.1	0.23	18.0	0.27	17.8	0.45	17.9	0.27	18.0	0.32
20.6	20.9	0.34	20.9	0.26	20.9	0.28	20.6	0.35	20.8	0.31
27.5	28.1	0.37	28.2	0.23	27.6	0.26	27.8	0.25	27.9	0.28
27.5	27.9	0.38	28.0	0.55	27.7	0.46	27.7	0.42	27.8	0.46
37.7	38.2	1.07	38.0	0.78	38.7	0.35	38.3	0.18	38.3	0.69
41.2	42.07	0.35	41.8	0.58	41.6	0.88	41.8	0.43	41.8	0.59
67.8	37.6	1.55	68.6	0.55	68.8	0.58	69.7	0.57	68.7	0.92
68.8	70.5	0.60	70.4	0.42	69.7	1.05	70.7	0.73	70.3	0.73
103.1	102.9	0.76	103.5	0.90	104.0	1.54	104.0	1.68	103.6	1.28
139.5	139.5	1.64	140.0	1.99	137.6	2.80	140.8	4.17	139.5	2.82

PO2-Measurements

	Svr	inge	Capi	illary	Mi Sam		İ	cro nple	ТО	ΓAL
Target	\overline{x}	1SD	\overline{x}	1SD	$\overline{\mathcal{X}}$	1SD	$\overline{\mathcal{X}}$	1SD	$\overline{\mathcal{X}}$	1SD
0.0	1.07	0.47	0.89	0.47	0.83	0.36	0.70	0.57	0.87	0.47
21.0	20.9	0.53	21.1	1.50	20.7	0.60	20.6	1.05	20.8	1.00
44.7	44.4	1.00	44.4	1.12	43.3	0.64	43.3	1.68	43.8	0.93
76.0	67.6	1.55	68.6	0.55	68.8	0.58	69.7	0.57	68.7	0.92
96.2	95.7	0.70	96.7	0.96	97.5	0.88	97.1	1.10	96.7	0.92
135.6	137.3	3.25	136.3	1.24	137.4	1.38	137.8	1.14	137.2	1.95
300.7	290.8	3.60	295.1	1.87	294.12	8.18	293.7	3.06	293.4	4.81
344.0	336.9	6.65	342.1	4.07	343.6	3.48	343.6	9.93	341.5	6.55
501.2	492.1	11.11	489.1	7.19	486.7	8.39	494.3	9.30	490.5	9.11
659.5	640.1	12.61	647.7	11.80	644.6	12.22	641.6	20.55	643.5	14.75

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1 Introduction

Analyzer Description



Fig. 1-1: AVL COMPACT 3

- The AVL COMPACT 3 is an automatic microprocessor controlled pH / Blood Gas Analyzer with an integral thermal printer.
- High safety, zero risk sample port and waste level control eliminate contamination and infection hazard.
- A complete pH / Blood Gas analysis is performed on only 55 μl of whole blood with obvious benefits in neonatology, pediatrics and geriatrics.
- An optimized user interface reduces the requirement for extensive user training.
- AVL zero-maintenance electrodes fit perfectly to the low maintenance concept of the AVL COMPACT 3.
- Quick and precise analysis is completed within 20 seconds from sample introduction to results.
- Lowest consumables and calibration gas requirement of any comparable analyzer, ensures continued cost savings.
- Product design and AVL quality combine to ensure ultimate performance, reliability and economy.
- Extensive self-diagnostic software, as featured on all AVL analyzers.

Intended Use

The AVL COMPACT 3 pH / Blood Gas Analyzer is intended to be used for the measurement of pH, PCO_2 and PO_2 in samples of whole blood.

Clinical Significance

pН

The pH-value of the blood, serum or plasma, may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH-value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH-values are generally classified as:

pH < 7.4

- primary bicarbonate deficit metabolic acidosis
- primary hypoventilation respiratory acidosis

pH > 7.4

- primary bicarbonate excess metabolic alkalosis
- primary hyperventilation respiratory alkalosis

An increase in blood, serum or plasma pH (alkalemia) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO₂ due to hyperventilation.

A decreased pH-value (acidemia) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H⁺-ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic; as the result of obstructive or restrictive respiratory diseases.

PCO₂

The PCO₂-value of arterial blood is used to assess how well the body eliminates carbon dioxide in relation to the metabolic rate of CO₂ production. A PCO₂ below the normal range is termed respiratory alkalosis and indicates hypocapnia, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial PCO₂ above the normal range is termed respiratory acidosis and indicates hypercapnia, a sign of hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

PO₂

The PO_2 -value of arterial blood has become the primary tool for the evaluation of arterial oxygenation status. Values below the normal arterial PO_2 (arterial hypoxemia) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decreased cardiac output, increased oxygen demand, anatomical heart defect, low inspired O_2 content). Generally, PO_2 -levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg PO_2 provides a 97% saturation level, and a level greater than 100% cannot be achieved.

Handling the Analyzer

Location

For correct, trouble-free operation, the following environmental specifications must be observed:

- Ambient temperature: +15 °C to + 32 °C (50 °F to 90 °F).
- Avoid direct sunlight.
- Avoid hazardous gases and vapors.
- Relative humidity: 20 90 %.
- Avoid locations beside strong electromagnetic fields (electric motors, transformers, X-ray apparatus etc.). Avoid the use of cellular telephones close to the device.
- Avoid vibration, use a solid surface.
- Allow sufficient space (at least 20 cm / 8 Inch minimum) around the analyzer for air circulation and electrical supply.

General Information

The AVL COMPACT 3 should be switched on at all time. For switch-off periods of more than 12 hours, the "shutdown procedure" described in chapter 3 must be performed.

- Do not place liquids on top of the analyzer.
- Perform regular quality control tests (for further information, please refer to chapter 5).

Handling Blood and Blood Products

Hygienic Handling of Blood

Always handle blood with caution, as it may contain hazardous biological substances.

WARNING: Waste liquids must be disposed of in accordance with local regulations (biohazard).

Handling AVL Reagents

NOTE: AVL Medical Instruments cannot guarantee the performance of the analyzer if any of the following situations occur:

- Reagents other than those recommended are used.
- Expiration dates of reagents have been exceeded.
- Reagents are not used according to AVL's recommendations.
- The procedures described in this manual are not followed.

Precaution

AVL Deproteinizer contains sodium hypochlorite (≤ 2.0 % active chlorine). Do not swallow the solution, avoid eyes and skin contact. In case of contact wash the affected area with plenty of water. In case of eye contact consult a physician as soon as possible.

Storage

Store AVL reagents in accordance with the information displayed on the package label, allow reagents to stabilize at ambient temperature before use.

Decontamination

AVL recommends the following decontamination procedures. Decontamination should be performed in accordance with typical laboratory regulations.

This decontamination should be performed periodically to minimize the risk of infections (incl. hepatitis virus and HIV).

The purpose of this procedure is to minimize the risk when replacing items that were in direct contact with blood.

NOTE: Always used approved, protective gloves!

The following parts of the device have to be decontaminated:

Daily

- Fill port area
- Keyboard
- Surfaces

As needed

• Sample path

Reagents

NOTE: Use liquid disinfectants only. Do not use sprays!

AVL Deproteinizer

Composition

Aqueous solution of NaOCl containing ≤ 2.0 % active chlorine.

Hazards identification

Due to the basic and oxidizing character of the reagent ("Deproteinizer") local irritations after contact with eyes, skin or mucous membranes cannot be excluded.

First aid measures

After inhalation: fresh air, drink plenty of water

After skin contact: rinse with plenty of water, remove contaminated

clothes

After eye contact: rinse with plenty of water, consult a doctor

If swallowed: drink plenty of water, avoid vomiting, and consult a

doctor

NOTE: When Deproteinizer is handled and used properly, no ecological problems are to be expected.

Disinfectant

A commercially available alcoholic disinfectant containing aldehyde should be used (e.g.: Meliseptol). Please refer to the product description of the surface disinfectant.

NOTE: Do not use the disinfectant for internal decontamination of the sample path!

Fill port area

For decontamination AVL Deproteinizer is especially recommended. You may also use a commercially available alcoholic disinfectant containing aldehyde.

Sample drip tray

The sample drip tray prevents contamination of the bottle compartment (in case of improper sample introduction). Decontaminate a dirty sample drip tray with a cloth or gauze pad saturated in disinfectant.

Procedure

- 1. Open bottle compartment cover.
- 2. Pull sample drip tray out.
- 3. Clean and decontaminate or replace it.
- 4. Close bottle compartment cover.

Fill port

Decontaminate fill port with a cloth or gauze pad saturated in disinfectant.

Procedure

1. Activate:

User programs ? YES 6x VES

System test ? YES

Electrodes ? YES

- 2. Open flap.
- 3. Decontaminate fill port.
- 4. Close flap.
- 5. Press the key **ESC** twice upon completion of this maintenance procedure.

The system performs a washing/drying procedure and will return to the "READY" screen.

Flap

Decontaminate the inside and outside of the flap with a cloth or gauze pad saturated in disinfectant.

Procedure

1. Activate:

User programs ? YES 6x 🤝

System test ? YES

Electrodes ? YES

- 2. Open flap.
- 3. Decontaminate the inside and outside of the flap and wait until disinfectant has dried.
- 4. Close flap only after disinfectant has dried completely to avoid damaging the lacquer when reopening the flap.
- 5. Press the key **ESC** twice upon completion of this maintenance procedure.

The system performs a washing/drying procedure and will return to the "READY" screen.

Keyboard

Decontaminate the keyboard with a cloth or gauze pad saturated in disinfectant.

NOTE: Decontaminate with damp cloth only using a disinfectant. Do not use sprays!

Surfaces

Decontaminate all outside surfaces and cover with a cloth or gauze pad saturated in disinfectant.

Sample path / Measuring chamber

Cleaning with AVL Deproteinizer should be performed only when the measuring capillary is contaminated (protein residue) or if components of the measuring path are being replaced.

Such cleaning process basically interferes with the measuring system and the electrodes. They must be conditioned afterwards.

The decontamination agent is introduced via the fill port.

If necessary decontaminate the measuring chamber specially the connecting pieces with a cloth saturated in disinfectant.

Procedure

Activate:

User programs ? YES 3x 🤝

Maintenance ? YES 2x 😾

Cleanin9 ? YES

Perform cleaning according instructions on the display.

NOTE: After reinstalling of the decontaminated electrodes at a later time or a new electrode perform two measurements with a wetting agent (e.g. whole blood) to moisten the system.

Handling the Electrodes

Handle the electrodes with great care to prolong their operation life.

- Avoid contact between the electrode tip and hard surfaces.
- Never allow the electrodes to dry out, or store them unprotected.

For details, please refer to chapter 9, section "Care and Maintenance of pH / Blood Gas Electrodes", and chapter 12, section "Care and Maintenance of Remembranable pH / Blood Gas Electrodes".

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2 Description of the Analyzer

Main Features

The AVL COMPACT 3 is a fully automatic microprocessor-controlled analyzer for quantitative "in-vitro" measurement of whole blood of the following analytes:

pH hydrogen ion activity

PCO₂ partial pressure of carbon dioxide

PO₂ partial pressure of oxygen BP actual barometric pressure

Based on measured parameters, in conjunction with patient temperature, ctHb and FIO_2 , the following parameters can be calculated:

BE base excess

 $\begin{array}{ll} BE_{ecf} & base\ excess\ of\ extra\ cellular\ fluid \\ BE_{act} & base\ excess\ at\ actual\ oxygen\ saturation \end{array}$

BB buffer base

HCO₃ actual bicarbonate

 $cHCO_3$ standard bicarbonate at a $PCO_2 = 40$ mmHg

 $ctCO_2$ PCO_2 of 40 mmHg

pH_{st} standard pH value at a PCO₂ of 40 mmHg

AaDO₂ arterial-alveolar oxygen partial pressure difference

cH⁺ hydrogen ion concentration

SO₂ oxygen saturation ctO₂ oxygen content

Shunt measurement for the direct mixture venous blood in the

oxygenated circulatory system

Measurements

The AVL COMPACT 3 analyzer is equipped with a sample detection system, which identifies air bubbles in a sample, controls the positioning of a sample in the instrument, and determines the volume of a sample. With a blood sample volume of at least $55~\mu l$ in place, an automatic Blood Gas measurement is performed.

With a blood sample volume of > 25 to $55 \mu l$ (Microsampler) a semi-automatic measurement of pH, PCO_2 and PO_2 will be performed.

Calibration

The following calibrations are initiated and performed automatically:

- Main calibration
- pH 1P calibration

The following calibrations are operator-initiated calibrations and will be performed automatically:

- pH 2P calibration
- Gas 2P calibrations

For details, please refer to chapter 6, "Calibrations".

Analyzer Components

Display and Keys



numeric keypad

Fig. 2-1: Display

Measured results, calculated parameters, and diagnostic informations appear on a four-line alphanumeric LCD display.

The keys and the numeric keypad in conjunction with the display provide control of all analyzer functions:

- measurements
- data input
- programming
- maintenance
- system test

Thermal Printer

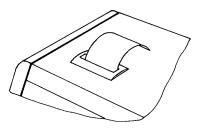


Fig. 2-2: Thermal printer

The analyzer is equipped with a 24-column thermal printer using special (58 mm) wide paper with one heat-sensitive surface.

The following data can be printed out:

- measured values
- calculated values
- calibration data
- electrode voltage
- system messages

Cover

It is essential to ensure the cover of the analyzer is closed during measurements and calibrations to prevent electrical interference and maintain temperature stability of the measuring system.

The cover can be held in an open position using the door rod to secure the door.

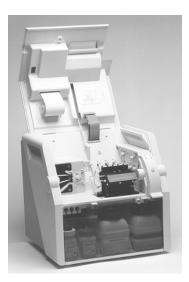
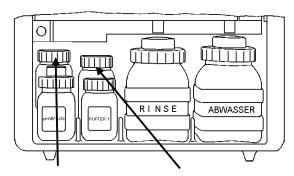


Fig. 2-3: View with open top cover

Bottle Compartment

In the bottle compartment the following reagents / containers are required

- Waste
- Rinse
- Buffer Type 1
- Buffer Type 2
- pH Reference Solution
- Cleaning Solution



Cleaning Solution

Buffer Type 2

Fig. 2-4: Reagents

NOTE: The ambient temperature for storing all reagents ranges from $5 \, ^{\circ}\text{C}$ to $30 \, ^{\circ}\text{C}$ ($41 \, ^{\circ}\text{F}$ to $86 \, ^{\circ}\text{F}$).

Waste

All liquids used by the analyzer are collected in the Waste container.

CAUTION: A trouble-free wash and dry cycle can be ensured only if the system is completely sealed. The Waste container lid must be tightly closed.

Rinse

The Rinse is used:

- to wash out the sample;
- to wash out the calibration solution.

Buffer Type 1 (pH = 7.383)

The Buffer Type 1 is used to determine the first point of a pH calibration.

Buffer Type 2 (pH = 6.841)

The bottle is placed behind the Buffer Type 1 bottle inside the bottle compartment.

The Buffer Type 2 solution is used to determine the second point of a pH calibration.

pH Reference Solution

This solution is pumped into the pH-reference electrode by means of a KCl pressure circulation system and the sample.

The pH Reference Solution is transported only if the bottle cap is closed tightly.

Cleaning Solution

The bottle is placed behind the pH Reference Solution inside the bottle compartment.

A cleaning cycle is automatically performed after 50 samples during the next main calibration.

CAUTION: Do not mix or refill reagents.

Use only AVL reagents.

Sample Fill Module

This module consists of the following parts:

- Flap
- Fill port and tube
- Sample drip tray

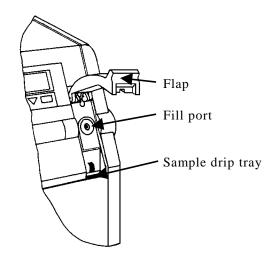


Fig. 2-5: Sample fill module

Flap

The flap has to be opened for a sample input.

CAUTION: If the flap is opened by mistake, the running action will be interrupted. The analyzer prompts the operator to close the flap and a wash/dry cycle will be performed.

Fill Port and Tube

The fill port (see Fig. 2-5) allows samples to be injected or aspirated from

- syringes,
- AVL Microsampler and
- capillaries without the need of adapters.

Sample Drip Tray

The sample drip tray is placed on the lower end of the fill module to avoid sample spilling. The tray is replaced as part of the scheduled maintenance procedures or when it becomes very soiled.

Description of the Sample Path

Fill Port

The sample is injected or aspirated into the fill port of the AVL COMPACT 3 using a syringe, capillary or AVL Microsampler.

The fill port is made of soft PVC and serves as an interface between the sample container and the sample path. The fill port is designed so those samples can be injected or aspirated via syringe, capillary or Microsampler without the need of an adapter.

The sample flows through the preheating tube.

Sample Inlet Path

The metal sample inlet path heats the sample up to 37° C.

The sample inlet path is also the first contact for sample detection and the first contact path $(K_0 - Mini Sample)$.

Measuring Capillary

The analyzer aspirates the sample from the sample inlet path into the measuring capillary.

In the measuring capillary, the sample contacts the electrodes. Before the sample reaches the measuring chamber valve it passes the second electrical contact for sample detection. In the measuring capillary, an electrical contact for sample detection is positioned between the PO_2 and PCO_2 Electrode. The AVL COMPACT 3 detects the sample and controls the filling of the measuring capillary by means of contact paths.

After the pH blood gas measurement is completed, the sample is moved into the waste bottle.

Measuring Chamber Valve

The electromagnetic measuring chamber valve closes the measuring chamber and avoids the direct filling of a syringe sample into the measuring chamber. The sample is pushed into a bypass tube. This construction ensures a continuous and bubble-free filling of the measuring chamber. It also prevents electrode damage from excessive pressure.

Measuring Chamber Module

The measuring chamber module consists of the following parts:

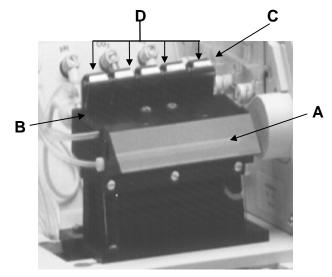


Fig. 2-6: Measuring chamber module

- (A) measuring capillary
- (B) measuring chamber block
- (C) measuring chamber valve
- (D) electrodes

Measuring Capillary

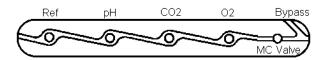


Fig. 2-7: Measuring capillary

In the measuring capillary the Blood Gas Electrodes and the pH Electrode are in direct contact with the sample to measure the Blood Gas parameters and the pH-value.

The measuring capillary is permanently illuminated so that the entire aspiration cycle can be observed.

Measuring Chamber Block

The entire module is thermostated at 37 °C.

Measuring Chamber Valve

The measuring chamber solenoid valve is located at the right end of the measuring chamber block.

This valve prevents direct access from the pre-induction tube (i.e. syringe injection) to the measuring chamber module to avoid damage of the electrodes.

Electrodes

The electrodes are inserted into the measuring chamber block from the rear. The electrode tips project into the measuring capillary thus come into contact with the sample material.

The electrodes are color-coded for easy identification.

Listed from left to right:

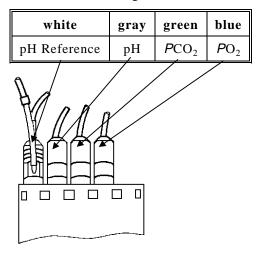


Fig. 2-8: Electrodes

Peristaltic Pump

The peristaltic pump is used to transport all samples and liquids inside the analyzer.

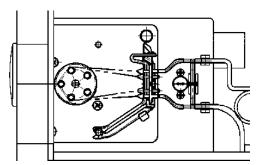


Fig. 2-9: Peristaltic pump

Rear Panel

Warning and identification plates with model and serial numbers are located on the rear panel of the unit.

NOTE: Only a trained service engineer is authorized to open the rear panel.



Fig. 2-10: Rear panel

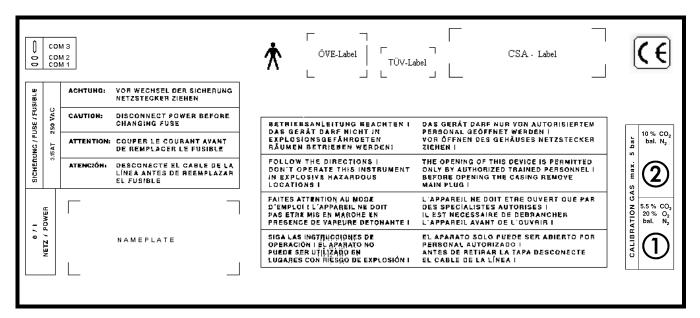


Fig. 2-11: Warning and identification plates

Interfaces

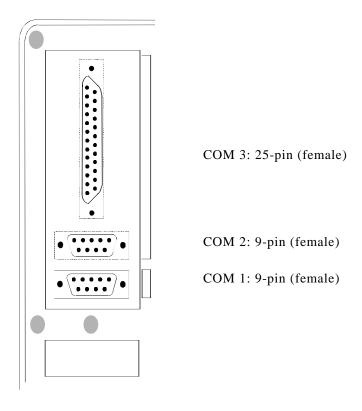


Fig. 2-12: Interface

The standard bi-directional interface (RS232 C, Submin. D-connector) enables the user to connect the analyzer with a Host Computer, an external printer or ticket printer.

In addition, the unit is provided with an interface option for a Bar code scanner and for data link with an AVL Oximeter or an AVL Electrolyte Analyzer and / or with an external service modem.

Gas Connections

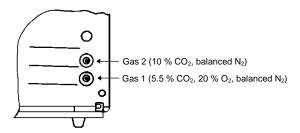


Fig. 2-13: Gas connections

Connections for gas tubing are located in the lower right corner of the rear panel.

Power Switch Module

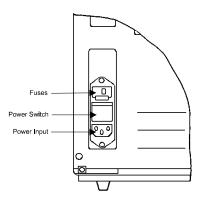


Fig. 2-14: Power switch module

This module consists of a power switch, power input, fuses, and a power line filter.

Operator Interface

Display

The display helps you to operate the analyzer. When the unit is ready for measurement, the display reads as follows:

READY 10:09 For measurement open the flap User programs ?

First line: current status of the analyzer, actual time.

Second and third line: display instructions, alarms and measuring values. Fourth line: indicates user programs and questions; selection,

activation and data input.

Keypad

The keypad in conjunction with the display provides control of all analyzer functions

Keys	Function	Data input
YES	activates user programsanswers indicated questionsconfirms indicated values	• confirms / completes data input
NO	• negates indicated questions	
$\overline{\mathbf{v}}$	 selects next function negates indicated questions	• input of time/date
	• selects previous function	• input time/date
ESC	 interrupts the program sequence interrupts all actions exits user programs jumps to previous menu 	• aborts data input

EXCEPT: calibrations and measurements: an interruption by pressing [ESC] must be confirmed by pressing [YES].

123 456 789 ½0+	• input of all numerical values Except: time / date
1/2	• input of signs
•	• at each key touch the cursor will be placed back for one digit, without deleting other digits

EXCEPT: patient number

Timeout

If no key was pressed, the analyzer automatically returns within 30 sec from each user program to $\,$ READY.

Exception: the user program "System Test".

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3 Installation / Shutdown

This chapter describes the installation and shutdown procedures.

Installation

After the AVL COMPACT 3 has been unpacked and placed in a location according to the requirements described in chapter 1, the following steps should be performed:

Check whether analyzer and accessories are complete and undamaged. Check contents against the supplied packing list.

If parts are missing inform your AVL representative. In case of damage inform your carrier immediately. Keep analyzer and packing material until any queries have been addressed.

NOTE: Packing may vary by country and slight variation from the accessories list.

Contact your AVL representative for your specific list.

Description

1 set dummy electrodes (four pieces) lamp 28 V 1 pcs. 1 pcs. 80 mAT / 250 V (F1/F2) 1.6 AT / 250 V (F3 / mains fuse) 1 pcs. 2 pcs. 3.2 AT / 250 V (F4) 1 pcs. nozzle cleaning needle 1 pcs. tubing set for peristaltic pump 1 pcs. fill port 1 pcs. quad ring seal for pH Reference Solution bottle (28.17 x 3.53 mm) 1 pcs. quad ring seal for measuring chamber $(1.06 \times 1.25 \text{ mm})$ 1 pcs. quad ring seal for waste (50.4 x 3.53 mm) 1 pcs. leak proof adapter (measuring chamber valve) 1 pcs. power cable ($\emptyset = 1.5 \text{ mm}^2$; length = approx. 2 m) sample drip tray 1 pcs. 1 pcs. operator's manual

Location

For correct, trouble-free operation, the following environmental specifications must be observed:

- Ambient temperature: +15 °C to + 32 °C (50 °F to 90 °F).
- Avoid direct sunlight.
- Avoid hazardous gases and vapors.
- Relative humidity: 20 90 %.
- Avoid locations beside strong electromagnetic fields (electric motors, transformers, X-ray apparatus etc.). Avoid the use of cellular telephones near the device.
- Avoid vibrations, use a solid surface.
- Allow sufficient space (at least 20 cm / 8 Inch minimum) around the analyzer for air circulation and electrical supply.

Solenoid Valve Relief Clamps

In the AVL COMPACT 3 analyzer, relief clamps are inserted under the solenoid valves to prevent tube damage.

Before installing the analyzer remove the relief clamps and reinsert it during shutdown procedure.

NOTE: Do not forget to remove the relief clamps, otherwise no proper start up operation will occur.

The clamps designed for this purpose can easily be removed by lifting the solenoid fixtures.

Slightly pull the armature of the valves when removing the relief clamps. Take care for the solenoid valve relief clamps, you will need it for a possible later shutdown.

Open the cover of the analyzer to gain access to the solenoid valves relief clamps.

Six of them (V3, V4, V5, V7, V11, V12) are located to the right of the measuring chamber (see Fig. 3-1), one to the right of the peristaltic pump (see Fig. 3-2).

Open the bottle compartment cover (transparent gray plastic) and remove the three solenoid valve red relief clamps from the solenoid valves (V6, V8, V10) in the bottle compartment (see Fig. 3-3).

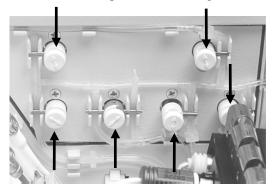


Fig. 3-1: Solenoid valve relief clamps - fill module

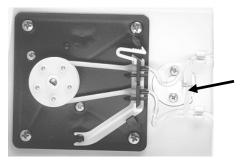


Fig. 3-2: Solenoid valve relief clamps - peristaltic pump

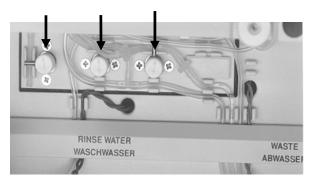


Fig. 3-3: Solenoid valve relief clamps - bottle compartment

Peristaltic Pump Tube

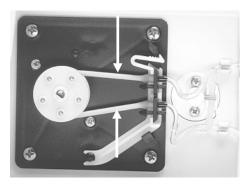


Fig. 3-4: Peristaltic pump tubes

Procedure

• Push end of tension lever to the right and slightly against the pump plate until it locks with a click.

Filling and Connecting the Bottles

Located under the measuring chamber and the fill module, the reagent compartment houses the fluid containers.

The screw-on caps with tubing for the containers are connected to the liquid circulation system which projects from the rear wall of the reagent compartment.

NOTE: Ensure to place the caps to the corresponding reagent bottles and pay attention, that no tube is folded.

Waste Bottle

Before screwing the cap on the Waste bottle, ensure that the ring seal is properly in place.

If the seal is in place, screw the cap onto the empty Waste container and insert the bottle into its socket in the bottle compartment.

NOTE: Ensure that the Waste bottle is completely airtight to allow a trouble-free operation.

Rinse, pH Reference Solution, Buffer Type 1, Buffer Type 2, Cleaning Solution

The necks of the bottles are sealed with aluminum foil. Remove the foil by cutting along the edge of the bottleneck.

NOTE: When removing the foil, make sure that the fluids are not contaminated.

NOTE: If you do not use the Rinse reagent, fill the bottle with distilled water and add one ampoule of Rinse Additive.

Screw the caps on the bottles and place them in their sockets in the bottle compartment.

NOTE: Before screwing on the cap of the pH Reference Solution bottle, ensure that the ring seal is properly in place.

Ensure that the cap is screwed on finger tight otherwise the pH Reference Electrode will not function properly.

After installing the pH Reference Solution, do not switch on the analyzer before a pH Reference Electrode has been installed!

Calibration Gas Connection

The AVL COMPACT 3 needs two different calibration gases.

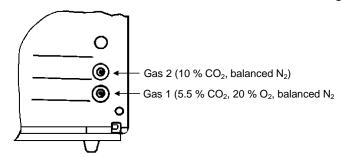


Fig. 3-5: Gas connection

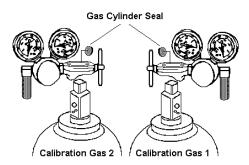


Fig. 3-6: Position of calibration gas cylinder

Procedure

- Install the pressure regulators on the new gas cylinders.
- Insert the new cylinders in the holder and secure them.
- Connect the tubes to the outlet of the gas reduction valve.
- Connect the tubes to the connector nipples on the rear panel of the AVL COMPACT 3.
- Open the valves of the gas cylinders again.

NOTE: Do not mix up bottles and tubes.

NOTE: The length of the gas tube is limited at 1m (3 ft). Avoid large distances between analyzer and gas cylinder.

Please contact your AVL customer support if larger distances are necessary.

Electrodes

NOTE: Zero maintenance pH / Blood Gas Electrodes do not require any preparation.

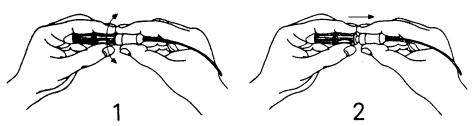


Fig. 3-7: Removal of transport housing

Before installing the remembranable electrodes remove transport housing (twist **(1)** and pull **(2)**) and fit them with a new electrode housing (see chapter 12, "Care and Maintenance of Remembranable pH / Blood Gas Electrodes").

NOTE: Save transport housing for possible storage or transport.

The electrodes do not require cleaning with electrode paste at this stage. Install the electrodes from right to left in the following sequence:

- PO₂ Electrode (blue)
- PCO₂ Electrode (green)
- pH Electrode (gray)

Pull out the electrode clips and insert the electrodes into the measuring chamber block.

Secure the electrodes with the clips and connect the electrode cables.

pH-Reference Electrode (white)

1. Carefully remove the protective caps from the pH Reference Electrode nipples. Connect the unmarked tube to the lower nipple and the yellow-coded tube to the yellow-coded upper nipple.

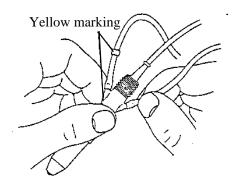
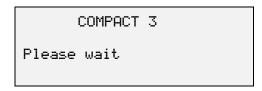


Fig. 3-8: pH Reference Electrode - yellow marking

Replace the pH Reference Electrode housing with a new one. Fill the pH Reference Electrode with pH Reference Solution, before inserting into the measuring chamber block.

- 2. Plug the power cord into an electrical outlet and switch on the analyzer.
- 3. The following display appears:



When the correct temperature is reached, the following display with the correct temperature appears.

During the warm up there is a conditioning of the PO_2 - and PCO_2 -electrode.



4. Check the automatic filling function of the pH Reference Electrode housing (see chapter 9).

If the pH Reference Electrode is filled, continue with item 5.

If the pH Reference Electrode was not filled:

Take pH Reference Electrode out of the measuring chamber.

NOTE: Do NOT disconnect cable and tubes!

Activate:

Maintenance? YES 1x

Ref. Electrode? YES

USER PROGRAMS Ref. electrode

Fill electrode ?

Press [YES]

This function activates the automatic filling of the pH Reference Electrode housing.

On completion of the filling procedure, the following display appears:

USER PROGRAMS Ref. electrode

Fill electrode ?

5. Press NO when the electrode is filled.

The permeability of the pH Reference Electrode diaphragm should be tested.

Carefully touch the electrode tip with a clean dry tissue.

USER PROGRAMS Ref. electrode

Check permeability?

Press YES to confirm.

Observe the electrode tip for the formation of a small droplet of pH Reference Solution.

USER PROGRAMS Ref. electrode

Check permeability ?

If no droplet has formed on the tip, press \overline{YES} to confirm and repeat this procedure, otherwise exit this program by pressing \overline{ESC} .

If again no droplet has formed replace the pH Reference Electrode housing in accordance with the instructions given in chapter 9, "Maintenance".

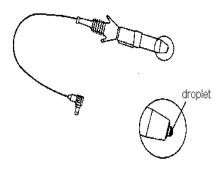


Fig. 3-9: pH Reference Electrode - droplet

If the droplet has formed, wipe it off carefully, insert the electrode into the measuring chamber and secure with the clip.

Press **ESC** to exit the program.

Inserting Printer Paper

- 1. Push the paper roll holder slightly to the side
- 2. Put a new roll of paper into the mounting support.
- 3. Insert the paper in the feeder.
- 4. Press the paper feed (black) button until the paper appears at the outside of the cover.

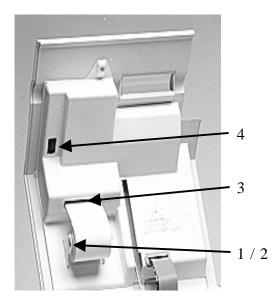


Fig. 3-10: Paper insertion

NOTE: The paper is heat-sensitive on one side only. Make sure that it is inserted correctly.

Shutdown

If the AVL COMPACT 3 is to be put out of use for a longer period of time, it is possible to activate the economy standby mode. During this time, the analyzer does not need Buffer Type 1 or Buffer Type 2, but the electrodes have the optimal conditioning.

If necessary, a "Manual Standby" or "Automatic Standby" can be activated. For details, see chapter 8 "Settings" section " Manual Standby" or "Automatic Standby".

This economy standby mode can be canceled at any time. After performing the necessary calibration the analyzer is READY.

Longer than 3 Days

If your AVL COMPACT 3 is to be shut down completely for more than 3 days, you have to empty the tubes, remove the electrodes from the measuring chamber and secure some of the tube valves with the relief clamps.

Procedure

READY 9:57
For measurement
open the flap
User programs ?

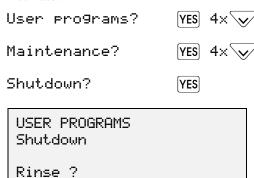
Rinse and Dry the Tubes

1. Take both tubes off the pH Reference Electrode and connect them with each other by means of a nipple. Close the two nipples of the pH Reference Electrode with the two supplied red stoppers.

NOTE: A capillary tube may also be used instead of a nipple.

Do not insert the ends of the capillary into the tubes deeper than 10 mm.

- 2. Empty Buffer Type 1, Buffer Type 2, pH Reference Solution and Cleaning Solution, rinse them, fill them with distilled water and put them back into the analyzer.
- 3. Activate:



Press YES.

A rinsing cycle is now activated during which the entire reagent inlet and outlet tubing system is rinsed.

Empty the bottles of Buffer Type 1, Buffer Type 2, pH Reference Solution, Cleaning Solution and Rinse.

USER PROGRAMS Shutdown

Dry ?

Press YES.

USER PROGRAMS Shutdown Dry activated

The liquids are aspirated and the tubing system is dried.

USER PROGRAMS Shutdown Switch off analyzer !

- 4. Switch off the power supply.
- 5. Close the valve of the calibration gas cylinders.
- 6. Insert the solenoid valve relief clamps.
- 7. Empty, decontaminate and dry the waste bottle and put it back into the analyzer.

Electrode Care

Disconnect the electrode cables and lift the electrode clips. The electrodes may now be removed.

NOTE: Reinsert the electrode clips to avoid losing them.

Storage for only one day

To prevent the electrodes from drying out fill the protective caps with:

• pH Electrode: Buffer Type 1

• *PCO*₂ Electrode: *PCO*₂/TCO₂ Filling Solution

• PO₂ Electrode: do not fill

• pH Reference Electrode: pH Reference Solution

and seal them with Parafilm®.

Transport (only for Remembranable Electrodes)

- Remove the electrode housing from the corresponding electrode.
- Fill the transport housing with the corresponding electrolyte (Exception: PO₂ Electrode):
- Remove the outside O-ring from the transport housing for opening the discharge pore

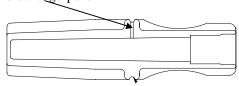


Fig. 3-11: Transport housing

• Fit the electrodes with the filled transport housing

Releasing the Peristaltic Pump Tube

Unlock tension lever. Push on hook-shaped until tension lever moves left and pump tube tension is released.

Releasing the Tubes

To prevent tube damage in the AVL COMPACT 3 analyzer during transport, relief clamps are inserted under the solenoid valves to.

NOTE: The clamps designed for this purpose can easily be removed by lifting the solenoid fixtures.

Six of them (V3, V4, V5, V7, V11, V12) are inserted to the right of the measuring chamber (see Fig. 3-12), one to the right of the peristaltic pump (see Fig. 3-13).

The remaining three red solenoid valve relief clamps have to be inserted (V6, V8, V10) in the bottle compartment (see Fig. 3-14).

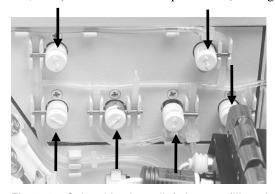


Fig. 3-12: Solenoid valve relief clamps - fill module

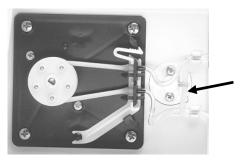


Fig. 3-13: Solenoid valve relief clamps - peristaltic pump

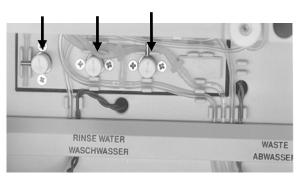


Fig. 3-14: Solenoid valve relief clamps - bottle compartment

Storage, Transportation

Protect the AVL COMPACT 3 with a dust cover during storage. For transportation purposes use the original shaped parts packing material.

4 PATIENT TESTING

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4 Patient Testing

This chapter describes routines used to operate of AVL COMPACT 3.

Sample Preparation

NOTE: Always observe the laboratory regulations, when collecting blood.

For capillary blood samples, it is advisable to use AVL capillary tubes, which contain a special Heparin coating.

The most advanced and user-friendly device for collecting arterial blood is the AVL Microsampler.

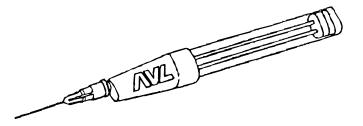


Fig. 4-1: AVL Microsampler

The use of very thin needles prevents common complications such as hematoma, thrombosis etc. which may occur after an arterial puncture.

NOTE: When the Microsampler needle punctures an artery, a pulsating blood flow filling of the capillary tube can be observed.

Continuous flow indicates that a vein has been punctured.

Important when Storing Blood

CAUTION: The higher the temperature of a sample, the faster and more intensive its metabolism (means change of Blood Gas and pH values).

The ideal temperature for long-term storing of blood is approx. 4° C (39 °F).

At this temperature the metabolism of a sample and, as a consequence, its oxygen consumption are lowest.

At a temperature of 4° C, a sample may be kept for up to two hours without significant changes of its Blood Gas and pH values.

When using an AVL Microsampler, the sample does not require icing for up to 30 min.

For details, please refer to chapter 13!

Sample Measurement

Syringe Measurement

Before a measurement can be performed, the analyzer must be in READY mode.

READY 17:20 For measurement open the flap User programs ?

NOTE: Before measurement, turn the syringe in your hand for about 10 seconds to mix the sample and remove any air by injecting it onto a cotton swab.

Open the flap.

MEASUREMENT Inject sample or select aspiration Aspiration ?

Insert the syringe into the fill port and inject the sample slowly.

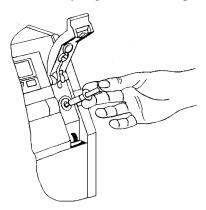


Fig. 4-2: Syringe measurement

As soon as the requisite sample volume is injected, an acoustic signal will sound and the following display appears:

MEASUREMENT 020 Remove syringe close the flap

Remove the syringe from the fill port and close the flap.

NOTE: If the flap is opened again while the sample is being aspirated and not closed before the countdown reaches 000, a continuous beep will sound until the flap is closed.

If the flap is opened during the measurement, the measurement will be aborted.

NOTE: Do not open the cover during measurements!

MEASUREMENT		019	
Edit	patient	data	?

The analyzer performs a fully automatic measurement.

The transparent, illuminated measuring channel enables the user to observe the movement of a sample and to identify blockages or air bubbles. During measurement, data input (input patient or sample related data) is possible.

If a barcode scanner is installed, it is possible to scan in the patient number during measurement (from sample stop up to reaching READY) as well as during the function "Data input" - "Patient number".

Please refer to chapter 8 "Settings", section "Interfaces" for further information.

The countdown running in the upper right corner of the display during the measurement ends with the display of measured pH, PCO_2 and PO_2 and one of the calculated values (for details, please refer to chapter 8, section "Settings" - "Display") and printout of the results.

CONDITIONING	091
PH 7.402 PC01 PO2 98.9 BE	2 41.0
P02 98.9 BE	4.0
Edit patient (data ?

On completion of the measurement, the results are displayed and printed out, and a gas conditioning is started. As soon as the countdown reaches 20 seconds, an asterisk (*020) appears to indicate that the flap can now be opened for further measurement (max. 4 times) before the end of the conditioning cycle is reached.

If the flap is not opened before completion of the countdown, the analyzer returns to Ready and the display will read as follows:

READY 17:22 For measurement open the flap User programs ?

Capillary or Microsampler Measurement

Before a measurement can be performed, the analyzer must be in the READY mode.

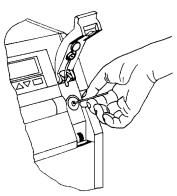


Fig. 4-3: Capillary measurement

READY 17:20 For measurement open the flap User programs ?

Open the flap.

MEASUREMENT Inject sample or select aspiration Aspiration ?

Press YES when "Aspiration ?" is indicated. Carefully insert the capillary into the fill port.

NOTE: At least 55µl sample volume is required!

If under "Settings" the function "Mini sample" was activated, the following display appears:

MEASUREMENT Sample is aspirated Mini sample? Press YES and only 60 µl sample will be aspirated. As soon as an acoustic signal will sound, remove the capillary and close the flap. The remaining sample volume can be used for measurements in another analyzer (oximeter or ISE).

If the displayed "Mini sample" was not confirmed by YES, the sample will be aspirated as long as the measuring chamber is completely filled.

After the acoustic signal will sound, remove the capillary and close the flap.

NOTE: If the flap is opened again, while the sample is being aspirated and not closed before the countdown reaches 000, a continuous beep will sound until the flap is closed.

If the flap is opened during the measurement, the measurement will be aborted.

NOTE: Do not open the cover during measurements!

MEASUREMENT	019
Edit patient	data ?

The analyzer performs a fully automatic measurement.

The transparent, illuminated measuring channel enables the user to observe the movement of the sample and to identify blockages or air bubbles.

During measurement, data input is possible.

If a barcode scanner is installed, it is possible to scan in the patient number during measurement (from sample stop up to reaching READY) as well as during the function "Data input" - "Patient number".

Please refer to chapter 8 "Settings", section "Interfaces" for further information.

The countdown running in the upper right corner of the display during the measurement ends with the display of measured pH, PCO_2 and PO_2 and one of the calculated values (for details, please refer to chapter 8, "Settings", section "Display") and printout of the results.

CONDITIONING 091 pH 7.402 PCO2 41.0 PO2 98.9 BE 4.0 Edit patient data ? On completion of the measurement, the results are displayed and printed out, and a gas conditioning is activated. As soon as the countdown reaches 20 seconds, an asterisk (*020) appears to indicate that the flap can now be opened for further measurement (max. 4 times) before the end of the conditioning cycle is reached.

If the flap is not opened before completion of the countdown, the analyzer returns to Ready and the display will read as follows:

READY 17:22 For measurement open the flap User programs ?

Micro sample

The micro sample is only offered as a measurement variation for capillary samples, smaller than $55\mu l$ and with a minimal volume of $25 \mu l$. The micro sample will automatically be identified during aspiration of the capillary sample. If the sample volume is greater than $25 \mu l$, the operator can choose micro sample measurement. If the question MICRO SAMPLE? is answered with $\overline{\text{NO}}$ or the time out has expired, the sample will be rejected with the error signal $\overline{\text{NO}}$ Sample! Thereafter, the analyzer carries out a wash-/dry cycle and conditioning process and returns to READY.

The PO_2 , PCO_2 and pH parameters can be chosen and measured individually, according to the order of the electrodes in the measuring chamber.

NOTE: The PO₂-measurement begins immediately after a micro sample has been detected (in this case, the sample is properly positioned as a result of the defined minimum volume) and the sample is then either disregarded or measured, depending on the chosen variation.

If a parameter (PCO_2 or PO_2) is chosen with \overline{YES} , the operator must position the sample by pressing \nearrow over the desired sample. The sensor must be completely covered by the sample. Press \overline{YES} to confirm the actual measurement.

If the parameter is in alarm, this particular parameter cannot be selected and is automatically passed without appearing on the display. The micro sample measurement is shown as MICRO on the display.

Procedure

READY 10:40 For measurement open the flap User programs?

Open the flap.

MEASUREMENT Inject sample or select aspiration Aspiration?

Press YES when ASPIRATION? is shown on the display. The sample will be aspirated.

A micro sample measurement is automatically performed when the sample volume is less than 55 μ l. If the sample is greater than 25 μ l, the following appears on the display:

MEASUREMENT Remove capillary close the flap Micro sample?

Close the flap and the following is shown:

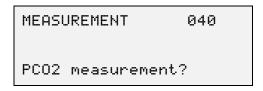
MEASUREMENT 034
Micro sample?

Confirm with YES .

If NO is pressed or after conclusion of time out, the sample will be washed out and the analyzer returns to the READY mode.

MEASUREMENT 032
P02 measurement?

Press $\overline{\text{YES}}$ to perform the PO_2 measurement. If the PO_2 measurement is not selected, the already scanned in values will also be canceled. After the PO_2 measurement, or when this is not selected by pressing $\overline{\text{NO}}$, the following appears on the display:



Press YES to perform the PCO_2 measurement.

MEASUREMENT 030 Pos. with UP

Sample positioned?

By pressing \bigcirc you can position the sample. The sample should be positioned uninterrupted. The sample should reach at least to the middle of the connecting capillary between the pH- and PCO_2 -electrodes. Confirm the correct position and start the measurement by pressing $\boxed{\text{YES}}$. After completion of the PCO_2 measurement, the pH-measurement will be offered. At the pH-measurement the pH-reference electrode as well as the pH-electrode have to be completely covered by the sample.

Printout of Results

Immediately after the results are displayed, the results are printed on the thermal printer.

For a detailed description of reports, see chapter 12, "Appendix", section "Description of Various Reports".

AVL COMPACT 3	
BLOOD GAS	
52005 67.0	
ACLD DACE DEDORT	header
ACID BASE REPORT	
Pat. Name:	
Age: 36 F	
Pat. no.: 18	patient data
Sample: CAPILLARY	patient data
cap.	
сар.	
M 47 N 07 45 54	
Mo, 17-No∨-97 15: 54	actual date / time
No.: 30	sample number
Baro 724.8 mmHg	air pressure
	<u>r</u>
#tHb A 15.2 g/dL	
#Temp 37.0 38.2 ÀC	input values
	input values
pH 7. 200 7. 184	
PCO2 17.0 17.9 mmHg	measured values
ý .	incasured values
BE - 19.3 mmol/l	
BEecf - 19.8 mmol/l	
BB 28.7 mmol/l	calculated values
HCO3 6.4 mmol/l	calculated values
0.4 111110171	<u> </u>
PO2 126.3 133.4 mmHg	
02sat 97.4 %	measured value
02Sat 97.4 %	calculated value
Op. I D. :	operator identity
#Input values	

NOTE: For details, please refer to chapter 8, "Settings".

To set the layout of this report, activate the program "Settings" "Report" - "Report Editor".

Password Option

If the function "Password" is activated in the program function "Settings" (for details see chapter 8, section "Barcode Scanner", or "Password"), the following condition for measurement is given:

Password - OFF

READY 08:35 For measurement open the flap User pro9rams?

The measurement can be performed as usual.

If a barcode scanner is installed, it is possible to scan in the patient number during measurement (within the sample stop time and before the measurement and calculated values appear on the display), as well as during the "Data input" function.

Please refer to chapter 8 "Settings", section "Interfaces" for further information.

Password - ON (Measurement - ON)

MEASUREMENT 08:35 For measurement open the flap Password?

The measurement can be performed without scanning in the password. In order to activate the program functions, either password-code 1 or password-code 2 must be scanned in.

The operator identification (OP. ID) can only be scanned in during the READY mode, with the use of the barcode scanner.

Details pertaining to the use of password-codecards can be found in chapter 8, "Settings", section "Password".

Password - ON (Measurement -OFF)

READY 08:35 Input password! Password?

A measurement can only be started, if a password-codecard is scanned in.

Scanning in the password-codecard 3

READY 08:35 For measurement open the flap Password?

The operator is only able to perform a measurement, but has no access to the program functions.

Scanning in the password-codecard 1 and 2

READY 08:35 For measurement open the flap User programs?

The operator is able to perform measurements and can also activate program functions.

CAUTION:

If a barcode scanner is installed, it is possible to scan in the patient number during measurement (from sample stop up to reaching READY) as well as during the function "Data input"

- "Patient number".

The operator identification (OP. ID) can only be read in with the barcode scanner during the READY mode.

Details pertaining to the use of password code cards can be found in chapter 8, "Settings", section "Password".

Parameter and Data Input

During and after a measurement, the user may enter or reset various parameters and patient-related data (e.g. the patient temperature). This can be done only for the current measurement.

If a barcode scanner is installed, it is possible to scan in the patient number during measurement (from sample stop up to reaching READY) as well as during the function "Data input" - "Patient number". Further it is possible to scan in the OP ID before a measurement (before the flap will be opened). Standard values (e.g. the patient's temperature, FIO_2 etc.) are default settings, which may be modified if necessary.

Parameter Input

The input of patient-related and sample-specific data overwrites the preset default values for the current measurement.

The data input is possible during measurement or immediately thereafter, as long as the results are displayed.

During the measurement

MEASUREMENT 019
Edit patient data ?

Press [YES].

USER PROGRAMS Edit patient data Parameters input ?

Press YES .

Select the desired parameter with \bigvee or \bigwedge and confirm by pressing \bigvee ES.

After the measurement

CONDITIONING 091 pH 7.402 PCO2 41.0 PO2 98.9 BE 4.0 Edit patient data ?

Press YES .

NOTE: If none of the following parameters is selected before the measurement is finished, the analyzer automatically returns to the highest menu level (CONDITIONING or READY).

USER PROGRAMS Edit patient data

Parameters input ?

Press YES and select the desired parameter with or or and confirm the selected parameter by pressing YES.

The following parameters can be modified:

- Patient's temperature
- tHb value
- Hb-type for fetal and adult blood
- Fraction of inspired oxygen (FIO₂)
- Respiratory quotient (RQ)
- Half-saturation pressure (*P*50)
- Sample Type (cap. / art. / venous)

Modification of Patient's Temperature

Activate:

Parameters input? YES

Pat. Temperature? YES

The displayed temperature may now be varied with the numeric keypad.

Available input range: 14 °C ... 44 °C (57.2 °F ... 111.2 °F). Preset value: 37 °C

When you confirm the selected temperature with YES , the display will fade out

At this point, you may select another parameter with vor exit from the program by pressing ESC.

Modification of tHb Value

Activate:

Parameters input? YES 1× 🤝

tHb? YES

The displayed tHb value may now be varied with the numeric keypad.

Available input range: 1.0 ... 26.0 g/dL

Preset value: 15 g/dL

When you confirm the selected tHb value with YES, the display will fade out. At this point, you may select another parameter with or or exit the program by pressing ESC.

Modification of tHb Type for Fetal and Adult Blood

Activate:

Parameters input? YES 2x

Adult/fetal Hb? YES

The analyzer calculates the oxygen saturation values on the basis of a standard ODC (Oxygen Dissociation Curve).

This ODC is, however, different for normal adult blood and for children's blood.

On the display appears "adult" and "fetal"; the selected parameter is blinking. Select either "adult" or "fetal" by pressing or .

When you activate the blinking parameter with YES, the display will fade out.

At this point, you may select another parameter with or or exit the program by pressing ESC.

Modification of Fraction of Inspired Oxygen (FIO₂)

Activate:

Parameters input? YES 3× 🤝

FIO2? YES

This parameter is used to calculate the alveolar-arterial oxygen partial pressure difference (AaDO₂).

The displayed FIO_2 value may now be varied with the numeric keypad.

Available input range: 0.11 ... 0.99

Preset value: 0.21

When you confirm the selected FIO_2 value with [YES], the display will fade out.

At this point, you may select another parameter with or or exit the program by pressing ESC.

Modification of Respiratory Quotient (RQ)

Activate:

Parameters input? YES $4x\sqrt{}$ (or $3x\triangle$)

RQ? YES

This parameter is also used to calculate the alveolar-arterial oxygen partial pressure difference (AaDO₂).

The displayed RQ value may now varied with the numeric keypad.

Available input range: 0.71 ... 1.99

Preset value: 0.84

When you confirm the selected RQ value with YES, the display will fade out. At this point, you may select another parameter with or or exit the program by pressing ESC.

Modification P50 Value

Activate:

Parameters input? $\overline{\text{YES}}$ 5x $\overline{\checkmark}$ (or 2x \triangle)

P50? YES

The P_{50} value is defined as the oxygen partial pressure at which the hemoglobin is half-saturated with oxygen.

The displayed P_{50} value may now be varied with the numeric keypad.

P50 adult

Available input range: 15 ... 40 mmHg (2.0 ... 5.3 kPa)

Preset value: 26.7 mmHg

P50 fetal

Available input range: 10 ... 40 mmHg (1.3 ... 5.3 kPa)

Preset value: 21.5 mmHg

When you confirm the selected P_{50} value with [YES], the display will fade out.

At this point, you may select another parameter with $\sqrt{}$ or $\sqrt{}$ or exit the program by pressing |ESC|.

Modification of Sample Type

Activate:

Parameters input? YES $6x\sqrt{}$ (or 1x \triangle)

Sample type? YES

By pressing or or you can select between "arterial", "capillary" and "venous".

Confirm the selected sample type by pressing **YES** .

At this point, you may select another parameter with $\sqrt{}$ or $\sqrt{}$ or exit the program by pressing $\boxed{\mathsf{ESC}}$.

If the modification is finished press ESC, the corrected report is automatically printed.

NOTE: It is possible to select the corresponding parameter with $\sqrt{}$ and

For example: instead of pressing $6x \checkmark$, press at the beginning 1x (for details, please refer to chapter 12, section "User Programs").

Input of Patient-Related Data

This patient related data input is possible during measurement or immediately thereafter, as long as the results are displayed.

During the measurement

MEASUREMENT 019
Edit patient data ?

Confirm by pressing [YES] and activate:

Parameters input? NO

Edit patient data? YES

Select the desired parameter with vor and confirm with YES.

After the measurement

CONDITIONING 091 pH 7.402 PCO2 41.0 PO2 98.9 BE 4.0 Edit patient data ?

Confirm by pressing YES and activate:

Parameters input? NO

Edit patient data? YES

Select the desired parameter with \checkmark or \land and confirm with \land

The following patient-related data can be entered:

- Patient number
- Patient's sex
- Patient's age

Entering	Patient's
Number	(Manual)

Activate:

Parameters input? NO

Patient data? YES

Patient number? YES

It is possible to enter a 10 digit patient number.

The first digit of the patients number is blinking.

With the numeric keypad the digit can be entered.

Confirm the correct digit by pressing **YES**.

At this point, you may select another parameter with $\sqrt{}$ or $\sqrt{}$ or exit from the program by pressing ESC.

Entering Patient's Number (Barcode)

If a barcode scanner was installed, it is possible to read the patient's number with the help of this active reading unit.

For details, please refer to chapter 8, "Settings", section "Interface".

Entering Patient's Sex

Activate:

Parameters input? NO

Patient data? YES 1x

Sex? YES

The display shows "male" and "female" and one of the parameters is blinking. Select either "male" or "female" with \checkmark or $^{^{\prime}}$.

Activate the blinking selection with **YES**.

At this point, you may select another parameter with vor or exit the program by pressing ESC.

Entering Patient's Age

Activate:

Parameters input? NO

Patient data? YES 2x 📈

Age? [YES]

You may now enter the patient's age between 0 and 99 using the numeric keypad.

When you confirm the correct age with YES, the display will fade out.

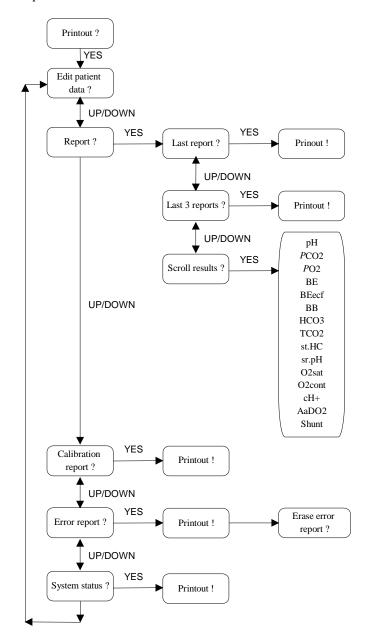
At this point, you may select another parameter with vor or exit the program by pressing ESC.

Printout

This user program enables you to obtain a printout of:

- last measurement report
- last three measurement reports
- calibration report
- error report
- system status

For details, please refer to chapter 12, section "Description of Various Reports".



Measurement Reports

If, for example, on completion of a measurement, the parameters have been modified or patient-related data have been entered, an updated measurement report, showing the modified parameters and data, may be printed out.

Activate:

User programs? YES 3x ✓

Printout? YES

Data input? YES

Data Input

This function enables the input of patient related and sample specific data. The input if these data overrides the preset default values for the last measurement. Confirm by pressing $\overline{[YES]}$.

For details, please refer to section "Parameter and Data Input", page 4-12.

Reports

Activate:

User programs? YES 3x 😾

Printout? YES 1×

Report? YES

USER PROGRAMS

Report

Last report?

Select either "Last report", "Last 3 reports" or "Scroll results" with or and confirm the selection by pressing YES.

When the selection "Last report" or the "Last 3 reports" is confirmed, the corresponding printout of the last report or the last 3 reports will be started.

Selecting "Scroll results" by pressing YES enables to scroll the results on the display.

USER PROGRAMS

PH 7.157

Results o.k. ?

Press or to scroll the results. If all the results are scrolled press [YES].

Exit from the program by pressing **ESC**.

Calibration Reports

It is possible to print out the report of the most recent calibration.

Activate:

User programs?

YES 3×

Printout?

YES 2× 💉

Calibration report ? YES

USER PROGRAMS

Please wait

At this point, the calibration report is printed out. On completion of the printout, the following display appears:

USER PROGRAMS

Printout

Calibration report ?

You may now select another parameter with or and activate it by pressing YES or exit the program by pressing ESC.

Error Report

This printout shows the last 20 error messages issued.

Activate:

User programs?

YES 3x

Printout?

YES 3x

Error Report?

YES

USER PROGRAMS

Please wait

The error report will be printed and then the following display appears:

USER PROGRAMS Printout Erase error report ?

Press YES if you want to delete the stored alarms, otherwise exit this program by pressing ESC.

System Status

This printout shows information about the general status of the analyzer:

- information about the last calibration data
- indicates the next pH 1P calibration and the next main calibration
- limits
- electrode voltages

Activate:

User pro9rams? YES 3x ✓

Printout? YES 4× 🗸

System Status? YES

For details, please refer to chapter 12, section "Description of Various Reports".

5 QUALITY CONTROL

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5 Quality Control

QC Measurement

Perform at least daily one quality control measurement with recommended AVL control material to check performance and measurement accuracy of the analyzer. Take an ampoule of the selected level out of the package and shake it. Tap the ampoule with your fingernail to remove any fluid from the ampoule neck. Break the ampoule open and fill the sample into a capillary.

NOTE: Use caution (gloves or tissue) to prevent injury while opening an ampoule.

Do not use the same ampoule or capillary twice.

Use only control material within one minute after opening the ampoule.

To perform a measurement, the analyzer must be in the READY mode.

Aspirate sample with adapter or capillary

READY 09:09 For measurement open the flap User pro9rams ?

Press YES.

USER PROGRAMS

QC measurement ?

Press YES to start the QC measurement.

QC MEASUREMENT For measurement open the flap

Open the flap.

QC MEASUREMENT Inject sample or select aspiration Aspiration ? Press YES and insert the tip of the ampoule adapter or capillary filled with the corresponding level of the desired QC material securely into the fill port.

The sample will be aspirated into the measuring chamber.

As soon as the requisite sample volume is aspirated, an acoustic signal will sound and the following display appears:

QC MEASUREMENT Remove capillary close the flap

Remove the ampoule adapter or the capillary from the fill port and close the flap.

NOTE: Do not open the flap during measurement!

The analyzer performs a QC measurement and detects automatically the corresponding level of the used control material.

On completion the results are displayed and printed.

QC MEASUREMENT 091 PH 7.651 PC02 ----PO2 78.9 BE *****

If the measured values are within the entered ranges of the specified level, the values will automatically be stored in the memory.

If one or more values are outside the ranges of the specified level, the operator can either reject the measurement values or select the appropriate values for storage in the memory.

QC MEASUREMENT 091 PH 7.651 PC02 ----PO2 78.9 BE **** QC Level 1 ?

By pressing and on you may now select the level which you have entered. Press YES to confirm your selection.

The analyzer starts with the conditioning and get READY for further measurements or QC measurements.

QC Edit Function

If you start with a new lot of QC material, it is necessary to enter correctly the lot number, expiration date and the specific target ranges.

NOTE: For lot numbers, expiration date and target ranges please refer to the package insert sheet of the recommended AVL control material!

Activate:

User programs? YES 1 imes 7

QC? YES 1× 😾

QC new lot? YES

Entering New Lot Number

USER PROGRAMS QC new lot

QC Level 1 ?

You may select Level 1, Level 2 or Level 3 by pressing or and confirm the selected level by pressing YES.

USER PROGRAMS Level 1

QC new lot data ?

Press YES .

USER PROGRAMS Level 1

Erase QC values ?

By pressing YES the stored QC data (values, date, lot number, expiration date, default QC limits) will be deleted. If no new QC data will be entered, confirm by pressing NO.

USER PROGRAMS Level 1 <u>3</u>142 QC new lot number o.k?

The first digit is blinking. You may enter or vary the number with the numeric keypad.

If the lot number was entered correctly, press YES to confirm.

Entering Expiration Date

Further you can enter the expiration date.

USER PROGRAMS Level 1 <u>00</u> 00 QC expir. date o.k. ?

The first digit (00 = month) is blinking.

You may now enter the digits.

With the numeric keypad month and year can now be entered (take care of the correct sequence!).

If the expiration date is entered correctly press YES to confirm.

Entering Target Ranges

The next display appears:

USER PROGRAMS Level 1 QC new lot data ?

Press .

USER PROGRAMS Level 1 QC range ?

Press YES to confirm.

USER PROGRAMS Level 1 Erase QC values ?

By pressing YES the stored QC data (values, date, lot number, expiration date, default QC limits) will be deleted. If no new QC data will be entered, confirm by pressing NO.

USER PROGRAMS Level 1 PO2 ?

By pressing \bigvee or \bigwedge you may now select PO_2 , PCO_2 or pH. Confirm the selected parameter by pressing \bigvee YES.

USER PROGRAMS PO2: <u>131</u> - 147 mmH9 QC Level 1 o.k. ?

Enter the correct range using the numeric keypad.

Press YES to confirm the correct value.

Press \bigvee or \bigwedge to select the ranges for PCO_2 and pH too.

Repeat operation for these parameters as described for PO_2 .

If the lot number, the expiration date and the target ranges for Level 1 are set correctly, press **ESC** twice to get the following display:

USER PROGRAMS QC new lot QC Level 1 ?

At this point you may now select Level 2 and Level 3 by pressing \bigvee or \bigwedge . Repeat operations as described for Level 1.

At the end of the procedure press **ESC** to return to the previous menu.

Following QC target ranges are set according to standards:

Level	Electrode	Range
	PO_2	131 147 mmHg
Level 1	PCO_2	1521 mmHg
	pН	7.18 7.24
	PO_2	98 114 mmHg
Level 2	PCO_2	3541 mmHg
	pН	7.37 7.43
	PO_2	7086 mmHg
Level 3	PCO_2	6169 mmHg
	pH	7.59 7.65

QC Statistics

This function allows the printout of the QC measurement statistical results.

USER PROGRAMS QC QC statistics ?

Press YES.

USER PROGRAMS QC Statistics QC Level 1

At this point you may select "Level 1", "Level 2", "Level 3" or "All Levels" by pressing or and confirm the selected level by pressing YES.

USER PROGRAMS
Please wait

The "QC Statistics Report" of the selected level (or all levels) for all parameters $(pH, PCO_2 \text{ and } PO_2)$ is now printed.

If the function "Multirule" (for details, please refer to chapter 8, section "AVL Multirule") is activated, corresponding information will be printed on the QC statistics report.

For details about "QC Statistics Report" printout, please refer to chapter 12. Exit this program by pressing **ESC** .

6 CALIBRATION

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Operator-Initiated Calibrations	
Main Calibration	
pH 1P Calibration	6-3
Gas 2P Calibration	6-3

6 Calibration

All calibrations are automatically performed by the AVL COMPACT 3 analyzer.

Automatic Calibrations

The following calibrations are automatically $\underline{initiated}$ and $\underline{performed}$ by the analyzer.

Main Calibration

This calibration is performed periodically every 12 hours or at a user programmable interval (2-12 hours).

The main calibration is performed by:

- Gas 1 (calibration point)
- Gas 2 (calibration point)
- Cleaning Solution

(an internal counter checks if more than 20 samples have been measured. If that is the case, a cleaning cycle will be performed during the next main calibration)

- Buffer Type 2 (calibration point)
- Buffer Type 1 (calibration point)

Buffer Type 1 and Buffer Type 2 will be measured for max. 3 times (4 times if one aspiration cycle was not detected). The number of cycles is dependent on the reproducibility of the values, the selected calibration interval and the quality of the electrodes.

pH 2P calibration

Buffer Type 1 and Buffer Type 2 will be measured in series for max. 4 times every 12 hours.

Gas 2P calibration

The analyzer performs a 2P calibration with Gas 1 and Gas 2 for the PO_2 and PCO_2 Electrode.

pH 1P Calibration

The analyzer performs pH 1P calibration with Buffer Type 1. This calibration can be programmed every 30 minutes or one hour (fixed) or drift dependent every 1, 2, or 3 hours (flexible).

For details, please refer to chapter 8, "Settings", section "Timings", "pH Calibration Interval".

Gas 1P calibration

A Gas 1P calibration will be performed in a time period of 3.5 minutes during standby mode and during READY.

Conditioning

To get READY the electrodes have to be conditioned with Gas.

There are two kinds of conditioning with Gas:

- interruptible after measurements
- non interruptible after all actions which have influenced the measuring path.

Depending on the kind of action performed before, the analyzer performs the corresponding conditioning. The conditioning that can be interrupted is signaled by an asterisk in the right upper corner of the display.

When the asterisk appears, the recalibration can be interrupted max. 4 times in running for a measurement.

Operator-Initiated Calibrations

All calibrations can also be initiated manually by the operator.

Activate:

User programs?

YES 2×

Calibrations?

YES

- 1. Main calibration
- 2. pH 2P calibration
- 3. pH 1P calibration
- 4. Gas 2P calibrations

Main Calibration

When this calibration is activated the following prompt can appear:

MAIN CAL.

Electrodes changed ?

Press YES if one or more electrodes have been changed, otherwise press NO to go on. This prompt does not appear if any electrode has been in alarm.

NOTE: After one or more electrodes have been changed a main calibration always has to be performed.

pH 1P Calibration

NOTE: If during the pH 1P calibration the display
"Electrode changed?" is confirmed by pressing YES the analyzer
performs automatically a pH 2P calibration!

If no electrodes have been changed respond to

PH 1P CAL.

Electrodes changed ?

by pressing NO.

Gas 2P Calibration

The Gas 2P calibration is identical for the PO_2 and PCO_2 Electrode. The display

GAS 2P CAL.

Electrodes changed ?

is confirmed by pressing $\overline{\text{YES}}$, if one ore both electrodes have been changed, otherwise press $\overline{\text{NO}}$.

7 DATA MANAGER

AVL	DataComm	2	7-1	L

7 Data Manager

To evaluate calibration, measurement and QC data a special software, AVL DataComm 2, is available.

For detailed information about data transfer, please refer to chapter 11, "Interface".

AVL DataComm 2

AVL intruduces a breakthrough in critical care data management – AVL DataComm 2. Designed for the Microsoft Windows operating environment, the AVL Datacomm 2's interface is simple and intuitive. You can collect data from as many as eight different analyzers – in real time.

The AVL DataComm 2 is designed to meet your lab's existing and future requirements.

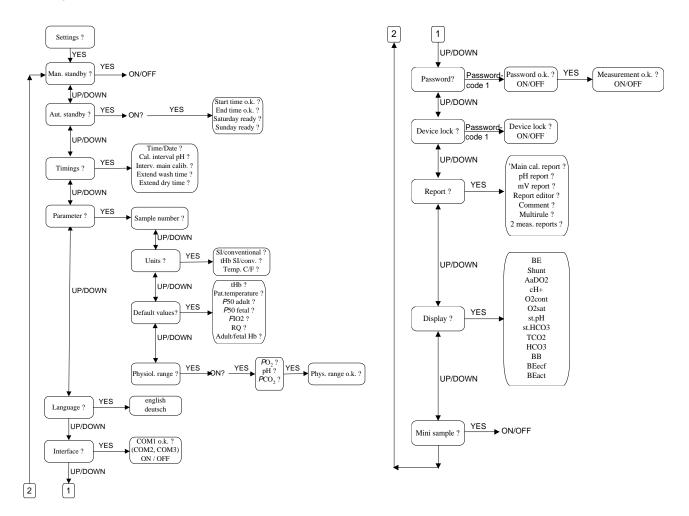
The AVL DataComm 2 is compatible with analyzers from several manufacturers, not just ours, so it's the most cost effective way to bring critical care data management to your lab.

Networking and connections to your LIS/HIS provide even greater flexibility.

8 SYSTEM FUNCTIONS

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8 System Functions



Activate:

User programs? YES 5x

Settings? YES

This program allows you to specify the following settings:

• Manual Standby? Activates / deactivates the economy standby mode.

• Automatic Standby? The timetable for the economy standby mode can

be programmed.

• Timings? Sets date, time, calibration intervals and extended

wash / dry time.

• Parameters? Programs default parameters valid for the

measurement.

• Language? Selects between two possible languages.

• **Interface?** Programs the interface.

• Password? Activation of the AVL COMPACT 3 by

authorized persons.

• Device Lock? Access to analyzer is totally blocked.

• **Report?** Activates / deactivates the print-out of:

pH report

- mV report

AVL Multirule

Comment

Activates / deactivates the report editor.

• **Display?** Selects the fourth calculated value, shown on the

display.

• Mini sample? During the measurement the question

"Mini sample" appears on the screen.

Manual Standby

Whenever the AVL COMPACT 3 is not used for a longer period, it is possible to activate the economy standby mode.

During this period the analyzer consumes no Buffer 1 and Buffer 2.

Activate:

Settings? YES

Man. Standby? YES

USER PROGRAMS

ON

OFF

Man. standby o.k. ?

On or OFF is blinking.

By pressing or you can switch between ON and OFF.

Activate the blinking selection by pressing **YES**.

Exit this program by pressing **ESC** twice.

The display reads as follows:

STANDBY MODE 15:41

User programs ?

Deactivate the entered standby mode in the same way it was activated or exit by pressing ESC.

Automatic Standby

In this mode it is possible to program a specific timetable when the AVL COMPACT 3 automatically enters or leaves the economy standby mode.

YES 1x

Activate:

Settings?

Autom. Standby? YES

USER PROGRAMS ON OFF Autom. standby o.k. ?

On or OFF is blinking.

By pressing or you can switch between ON and OFF.

Activate the blinking selection by pressing YES .

Now the start and end time of the automatic standby periods can be programmed. It is also possible to select, if the AVL COMPACT 3 should stay in the economy standby mode on Saturday and Sunday too.

USER PROGRAMS 20:00 Start time o.k. ?

Enter with the numeric keypad the correct start time (hour / minutes) and confirm by pressing [YES].

USER PROGRAMS <u>06</u>:30 End time o.k. ?

Enter the correct end time in the same way as the start time.

Confirm by pressing [YES].

The next display will read as follows:

USER PROGRAMS
Saturday ready ?

NOTE: Press YES if the analyzer should be ready for measurements on Saturday! That means that only the standby mode activated for the days during the week is valid (e. g.: 08:00 p.m. to 06.30 am). The analyzer is READY for the whole day.

Confirm this question by pressing NO, if for the whole weekend the standby mode should be valid (from Saturday 00:00 to Sunday 12:00 p.m.). If you have confirmed the question by YES, the following display appears:

USER PROGRAMS
Sunday ready ?

If you have confirmed by pressing $\[\]$, the analyzer is as READY as during the week, only the standby mode activated for the days during the week is valid. Confirm this question by $\[\]$ O , the standby mode is valid for the whole Sunday. At any time you are able to deactivate the standby mode in the same way as you have activated or exit by pressing $\[\]$ Exit this program by pressing $\[\]$ ESC .

Timings

This function allows to set date and time, calibration intervals and wash and drying cycles.

Activate:

Settings? YES 2x

Timings? YES

Date and Time

This function allows to set date and time.

Activate:

Settings?

YES 2×

Timin9s?

YES

Time/Date?

YES

USER PROGRAMS

Th, 04-Jul-96 14:10

Time/Date o.k. ?

On the display the day is blinking.

You may change the day shown by pressing \bigvee or \bigwedge .

Confirm the selected day by pressing YES .

The date is blinking.

Enter the selected date, month, year and time (hour / minute) step by step.

As soon as the last character is confirmed by pressing YES, the display will fade out.

At this point, you may either select another time setting by pressing or and activate the selected setting by pressing YES or exit from the user program by pressing ESC.

pH Calibration Interval

Activate:

Settin9s?

/ES 2× √√

Timin9s?

/ES 1× 😾

Cal. interval pH?

YES

USER PROGRAMS

fixed

flexible

Cal. interval pH ?

fixed or flexible is blinking.

You may now select whether the pH 1P calibration should recur at a fixed interval or be dependent on the pH-electrode drift [f(pH)].

Switch between "fixed" and "flexible" by pressing \bigvee or \bigwedge .

If "fixed" is activated by pressing YES, the following display will appear:

USER PROGRAMS 0.5 Hours 1.0 Hours Cal. interval pH ?

0.5 or 1.0 is blinking.

You may now set a pH calibration to recur either every 30 minutes or every hour. Switch between "0.5" and "1.0" by pressing $\sqrt{}$ or $\sqrt{}$.

Activate the blinking selection by pressing YES.

As soon as your selection is entered the display will fade out.

Main Calibration Interval

Activate:

Settings? YES 2x

Timings? [YES] 2× [VES] 2× [VE

Interv. main calib.? YES

USER PROGRAMS

Main cal.: 12 h

Cal. interval o.k. ?

You may now set an interval between 2 and 12 hours with the numeric keypad and confirm your selection by pressing [YES].

Extending the Wash Cycle

This function allows to activate or deactivate an extended wash cycle (6 seconds).

Activate:

Settings? YES 2x

Timings? YES 3x 🗸

Extend wash time? YES

USER PROGRAMS

ON

OFF

Ext. wash time o.k. ?

OFF or ON is blinking.

Switch between ON and OFF by pressing or .

Activate the blinking selection by pressing [YES].

As soon as your selection is entered, the display will fade out.

Extending the Drying Cycle

This function enables you to activate or deactivate an extended drying cycle (10 seconds).

Activate:

Settings?

YES 2x

Timin9s?

YES 4× V

Extend dry time?

YES

USER PROGRAMS

ON

OFF

Ext. dry time o.k. ?

OFF or ON are blinking.

Switch between ON and OFF by pressing $\overline{\hspace{-1em}\hspace{-1em}\hspace{-1em}\hspace{-1em}}$ or \triangle

Activate the blinking selection by pressing YES.

As soon as your selection is entered, the display will fade out.

At this point, you may either select another time setting by pressing \bigvee or and activate the selected setting by pressing \bigvee or exit this program by pressing \bigvee ESC .

Parameter

In addition to the values that are defined for each measurement, default values to all subsequent measurements can be programmed.

Activate:

Settings? YES 3x

Parameter? YES

The following default values can be selected:

- Sample number
- Units
- Standard values
- Physiological range

Sample Number

The sample number is a sequential number which increases by one with each measurement.

It may also be set or reset by the operator.

Activate:

Settings? YES 3x

Parameters? YES

Sample number? YES

USER PROGRAMS

Sample number 0000

Sample number o.k. ?

The first digit of the sample number is blinking.

You may enter the sample number with the numeric keypad.

Confirm the correct number by pressing YES .

As soon as the entered number is valid, the display will fade out.

At this point, you may select another parameter by pressing wand or exit this program by pressing ESC.

Units

Activate:

Settings?

YES 3×

Parameters?

YES] 1× 😺

Units?

YES

USER PROGRAMS Units

SI/conventional ?

Confirm by pressing YES.

The display shows SI and conventional and one of the parameters is blinking. Select either "SI" or "conventional" by pressing \bigvee or \bigwedge .

Activate the blinking unit by pressing YES .

As soon as the unit is entered, the display shows:

USER PROGRAMS Units

SI/conventional ?

Press vo get the next display.

USER PROGRAMS Units

tHb SI/conv. ?

Confirm by pressing YES.

The display shows SI and conventional, one of which is blinking.

If SI was selected before, SI is blinking.

Select "conventional" by pressing or for tHb, if the tHb value should be indicated in conventional units.

Activate the blinking selection by pressing YES .

As soon as the selection is entered, the display shows:

USER PROGRAMS Units

SI/conventional ?

Press vo get the next display.

The display shows $\mathbb C$ and $\mathsf F$ for entering the correct temperature unit; one of the temperature units is blinking.

Select either C or F by pressing \bigvee or \bigwedge .

Activate the blinking temperature by pressing [YES], the display will fade out.

At this point, you may select another parameter by pressing or or exit this program by pressing ESC.

Default Values

This function enables you to adjust the default parameter values.

Parameter	Unit	Default Values	Selectable Range
	[g/dL]	15	1.0 26.0
Total hemoglobintHb	[g/1]	150	10 260
	[mmol/l]	9.3	0.6 16.1
Dationt tomporature Tomp	[°C]	37.0	14.0 44.0
Patient temperatureTemp.	[°F]	98.6	57.2111.2
Half-saturation pressure . P50 adult	[mmHg]	26.7	15.0 40.0
	[kPa]	3.56	2.00 5.33
P50 fetal	[mmHg]	21.5	10.0 40.0
	[kPa]	2.86	1.33 5.33
Fraction of inspired oxygenFIO ₂	[-]	0.21	0.11 0.99
Respiratory quotientRQ	[-]	0.84	0.71 1.99
Adult / fetal HB	[-]	adult	adult / fetal

Activate:

Settings?

YES 3× 🤝

Parameters?

YES 2× V

Default values?

YES

Select the desired parameter by pressing or and confirm the selected parameter by pressing YES.

Proceed in the same way as described in chapter 4, section "Parameter Input during and after Measurement".

Exit this program by pressing **ESC** .

Physiological Ranges

This function allows you to set the upper and lower limits for PO_2 , PCO_2 and pH.

Parameter	Range (typical)	Increments	Specified Input Range
PO_2	70 99	1	0 - 200
pН	7.36 7.45	0.01	6.80 - 7.80
PCO_2	36 45	1	20 - 80

Activate:

Settings?

YES 3× 😺

Parameters?

YES 3× 🗸

Phys. range?

YES

USER PROGRAMS

ON

OFF

Phys. range o.k ?

ON or OFF is blinking.

Select either ON or OFF by pressing $\sqrt{}$ or \triangle .

Activate the blinking symbol by pressing YES.

USER PROGRAMS

Physiol. range

P02 ?

If ON is activated, you can select PO_2 , PCO_2 or pH by pressing \bigvee or and confirm the selected parameter by pressing \bigvee [YES].

USER PROGRAMS

PO2: 0 - 200 mmH9

Physi. ran9e o.k. ?

The first value is blinking - the displayed value may be varied with the numeric keypad.

Confirm the desired value by pressing YES .

The second value is blinking - the displayed value may be decreased by 1 by pressing $\overline{\psi}$.

Confirm the desired value by pressing YES.

NOTE: If the physiological range is activated, any additional information is printed on the report ("Flagging" of the measured value).

At this point, you may select another parameter by pressing or or exit this program by pressing ESC.

Language

With this function you can select the language to be used by your AVL COMPACT 3 in its displays and printouts.

Activate:

Settings?

YES 4×

Language?

YES

For example:

USER PROGRAMS

en9lish deutsch

Language o.k. ?

The activated language is blinking.

Switch between english and deutsch by pressing \bigvee or \bigwedge .

Activate the blinking selection by pressing [YES].

At this point, you may select another parameter by pressing or or exit this program by pressing ESC.

Interface

This function allows to set the interface protocol definition for data transfer.

Activate:

Settings?

[YES] 5× √

Interface?

YES

COM 1

The following display appears:

USER PROGRAMS ON OFF COM 1 o.k. ?

OH or OFF is blinking.

Switch between ON and OFF by pressing or Activate the blinking selection by pressing VES.

If ON is activated, the following display appears:

USER PROGRAMS COM 1 Mode ?

Confirm by pressing YES.

By pressing \bigvee or \bigwedge the following connections can be selected:

- 1. PC / Host / Printer
- 2. Ticket printer
- 3. Barcode

Confirm the selection by pressing YES.

By pressing or select the following display.

USER PROGRAMS COM 1 Baudrate ?

Confirm by pressing YES.

USER PROGRAMS 9600 Baudrate o.k. ?

Activate the corresponding baud rate by pressing YES, or select by pressing or another baud rate.

Available are: 1200, 2400, 4800, 7200 and 9600 baud.

Confirm the selection by pressing YES, the display will fade out. By pressing or select the next display.

USER PROGRAMS COM 1 Handshake ?

Confirm by pressing YES.

USER PROGRAMS NONE Handshake o.k. ?

By pressing vou can select between:

- 1. None
- 2. XON / XOFF

Confirm the selection by pressing YES.

Barcode Scanner

Connect and affix the barcode scanner to COM 1.

The barcode scanner is programmed with a Header (STX) and a Trailer (ETX). The reading units are pre-programmed for the code types

- 2aus5 Interleaved
- Codabar
- Code 128
- Code 39.

Note: If you use the original AVL IR barcode scanner the active scanning unit of the barcode scanner does not light red after being connected.

For further information about installation, please refer to chapter 11, "Interface".

Activate:

USER PROGRAMS ON OFF COM 1 o.k.?

ON or OFF blinks. Choose ON and confirm with YES. The following display appears:

USER PROGRAMS COM 1 Mode ?

Confirm by pressing \forall ES . By pressing \checkmark 2 times, the following is shown on the display:

USER PROGRAMS Barcode Mode o.k. ?

Confirm the selection by pressing $\overline{\text{YES}}$. Now the barcode scanner function is activated.

At this point, it is possible to scan in a patient number with the barcode scanner during measurement(from sample stop up to reaching READY) as well as in the "Data Input" - "Patient Number" function.

The operator identification (OP. ID) can only be read in with the barcode scanner during the READY condition.

Now you can select another option (PC / Host, Printer) by pressing or or leave the program by pressing ESC twice.

COM 2 / COM 3

The following description is valid for both interfaces.

The following display will appear:

USER PROGRAMS ON OFF COM 2 o.k.? ON or OFF is blinking.
Select either ON or OFF by pressing or or Activate the blinking symbol by pressing YES.

If ON is activated, the following display appears:

USER PROGRAMS COM 2 Mode ?

Confirm by pressing YES.

By pressing \bigvee or \bigwedge the following connections can be selected:

COM 2

- 1. PC / Host / Printer
- 2. Ticket printer
- 3. Datalink AVL 988-3 or AVL 9180
- 4. Datalink 912

COM 3

- 1. PC / Host / Printer
- 2. Ticket printer
- 3. Datalink AVL 988-3 or AVL 9180
- 4. Datalink 912
- 5. Modem

Confirm the selection by pressing YES, the display will fade out. By pressing or select the following display.

USER PROGRAMS COM 2 Baudrate ?

Confirm by pressing [YES].

USER PROGRAMS 9600

Baud rate o.k. ?

Activate the corresponding baud rate by pressing $\overline{\text{VES}}$, or select an other baud rate by pressing $\overline{\text{v}}$ or $\hat{\text{c}}$.

Available are: 1200, 2400, 4800, 7200 and 9600 baud.

Confirm the selection by pressing YES, the display will fade out. By pressing or select the next display.

USER PROGRAMS COM 2 Handshake ?

Confirm by pressing YES .

USER PROGRAMS NONE Handshake o.k. ?

By pressing \bigvee or \bigwedge you can select between:

COM 2 / COM 3

- 1. None
- 2. XON / XOFF (Software Handshake)
- 3. CTS / DTR (Hardware Handshake)

Confirm the selection by pressing [YES].

For details, please refer to chapter 11, "Interface".

Exit this program by pressing **ESC**.

Password

This function only allows the AVL COMPACT 3 to be activated by authorized persons.

The barcode scanner (including "Password-codecards" Fig. 8-1) with printed barcode is used to activate the analyzer. First the COM 1 in mode "Barcode" must be activated in the user programs "Settings" - "Interface".

Activate:

Settings?

[YES] $6 \times \sqrt{}$ (or $5 \times \sqrt{}$)

USER PROGRAMS Settings

Password?

NOTE: The password can only be activated with the password-codecard 1!

USER PROGRAMS ON OFF Password o.k. ?

ON or OFF blinks.

Select either ON or OFF by pressing or . Confirm the selected condition by pressing YES.

The following appears on the display:

USER PROGRAMS ON OFF Measurement o.k. ?

ON or OFF blinks.

Confirm the selected condition by pressing **YES**.

If Measurement o.k.? ON was selected, each measurement can be performed without reading the password-codecard. The user programs are only with password available.

You can leave the program (e.g. timeout after 2 minutes) by pressing \boxed{ESC} . The following is shown on the display:

READY 16:30 For measurement open the flap Password ? There are 3 access codes for the password. Each of these passwords are coded as barcode on the password-codecard. In addition to this password-code, an operator-identification-code can be adhered. This alpha-numeric operator-identification-code identifies the operator on the measurement protocol.

- Password-code 1 (corresponding to password-codecard 1).....superior
- Password-code 2 (corresponding to password-codecard 2).....authorized operator
- Password-code 3 (corresponding to password-codecard 3).....operator

NOTE: Access codes have different priorities:

- 1...highest access code
- 2... reduced access code
- 3...performance of measurements

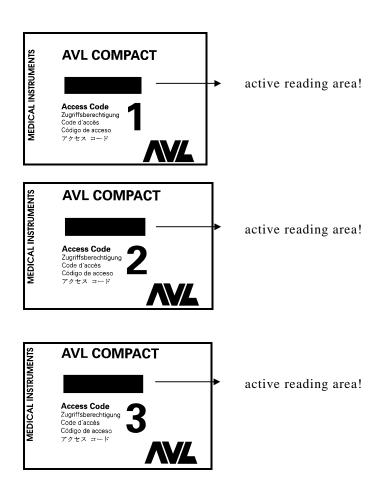


Fig. 8-1: Password-codecards with different access codes

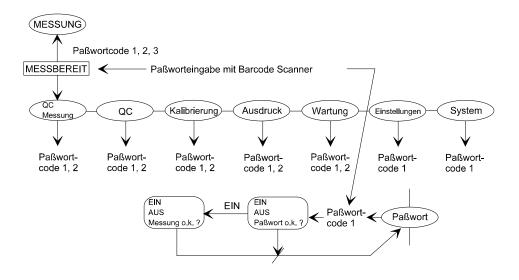


Fig. 8-2: Password

The figure above shows, which password-codecards give access in which area.

Device Lock

A password as well as an activated barcode scanner are necessary for this function. This should block the analyzer, making further access to the analyzer impossible.

Activate:

Settings? YES $7 \times \sqrt{}$ (or $4 \times \triangle$)

USER PROGRAMS Settings Device lock?

NOTE: This function can only be activated with the password-codecard 1!

USER PROGRAMS ON OFF Device lock o.k.?

ON or OFF blinks.

Confirm the selected condition by pressing [YES].

The following is shown on the display:

READY 16:35 Device locked ! Password ?

No further operation of the analyzer is possible without reading password-codecard 1.

For further details, please refer to section "Password", pg. 8-19.

Report

Activate:

Settings? YES $8x\sqrt{}$ (or $3x\triangle$)

Report? YES

Main Calibration Report

This function allows to activate or deactivate the report of the main calibration.

Activate:

Settings? YES $8x\sqrt{}$ (or $3x\triangle$)

Report? YES

Main cal. report? YES

USER PROGRAMS

ON

OFF

Main cal. report o.k.?

ON or OFF is blinking.

Switch between ON and OFF by pressing $\overline{\hspace{-1em}\hspace{-1em}\hspace{-1em}\hspace{-1em}\hspace{-1em}}$ or $extstyle \triangle$.

Activate the blinking selection by pressing [YES].

Exit this program by pressing **ESC**.

pH Report

This function allows to activate or deactivate the pH 1P calibration report.

Activate:

Settings? \overline{YES} 8x $\overline{\checkmark}$ (or 3x $\overline{\land}$)

Report? Y

PH Report? YES

USER PROGRAMS ON OFF PH Report o.k. ?

ON or OFF is blinking.

Switch between ON and OFF by pressing vor .

When you activate the blinking selection by pressing $\begin{tabular}{l} YES \end{tabular}$, the display will fade out.

Exit this program by pressing **ESC** .

mV Report

With this function you can activate the printout of electrode voltages, which are used for the determination of the measuring values.

With this mV report you can analyze calibration- / measuring problems (e.g.: drift, values out of range etc.)

Activate:

Settings? YES $8x\sqrt{}$ (or $3x\triangle$)

Report? YES 😾

mU Report? YES

USER PROGRAMS

ON

OFF

mV Report o.k. ?

OFF or ON is blinking, you can activate the printout of the electrode mV after each calibration cycle (for example: main calibration, pH 1P calibration,

Conditioning) by pressing .

Confirm by pressing YES .

For details, please refer to chapter 12, section "Description of Various Reports".

Exit this program by pressing [ESC].

Report Editor

This function enables the user to activate or deactivate an "individual" or a "standard" report editor.

Activate:

Settings? • 8x" (or 3x')

Report? • 3x"

Report editor? •

USER PROGRAMS standard i ndi vi dual Report o.k.?

AVL COMPACT 3 BLOOD GAS ACID BASE REPORT Pat. Name: Age: Pat. no. : Sample: CAPILLARY Th, 04-Jul - 96 13: 11 No.: 13 Baro 723.8 mmHg #tHb A 15.0 g/dL #Temp 37.0 ÀС 7. 208 рН PC02 16. 9 mmHg - 19.0 mmol/l ΒE BEecf - 19.5 mmol/l 28.9 mmol/l HCO3 6.5 mmol/l P02 129.6 mmHg 02sat 97.6 % Op. I D. :

......1. line2. line

fixed lines of the standard measurement report; these lines can be increased up to 30 lines with the "individual" report editor.

standard or individual is blinking.

#Input values

standard or individual is blinking.

Press or to select the other one.

Press YES to activate the blinking report.

Activate by pressing **YES**.

Example, how to program an "individual" report:

USER PROGRAMS Line 1: pH

Parameters o.k. ?

Press [YES] to activate pH in the first line.

By pressing you can select one of the following parameters for the first line:

РH	END	SPACE	Shunt	AaDO2
cH+	02 cont	02 sat	stpH	stHCO3
TC02	HC03	BB	BEecf	BE
P02	PC02	BEact		

Confirm the selected parameter by pressing YES.

Repeat the selection for the following lines in the same way.

With "SPACE" you insert such a blank line.

With "END" you determine the end of the report.

Comment

This function, allows to set a comment line up to 20 characters on the printout (e.g.: name of the hospital).

Activate:

Settings?

YES $8x\sqrt{}$ (or $3x\triangle$)

Report?

|YES| 4× 🤝

Comment?

YES

Available are: capital letters, small letters, numbers and special characters.

USER PROGRAMS

-

Comment o. k. ?

The first character is blinking.

Press \bigcirc or \bigcirc until the required character appears on the display.

Confirm your selection by pressing [YES].

The next character is blinking.

Repeat the operation to enter the required comment.

Exit this program by pressing **ESC** .

AVL Multirule

Activate:

Settings? YES 8x√√ (or 3x∕^)

Report? YES 5x ₩

Multirule? YES

USER PROGRAMS

ON

OFF

Multirule o.k. ?

OFF or ON is blinking, by pressing or or you can now activate or deactivate the AVL Multirules.

These Multirules are valid for the QC Statistics.

Confirm by pressing YES .

For details, please refer to chapter 11, section "Parameters and Equations".

2 Measurement Reports

Activate:

Settings? YES $8x\sqrt{}$ (or $3x\triangle$)

Report? YES 6x

2 meas. reports? YES

USER PROGRAMS

ON

OFF

2 meas reports o.k. ?

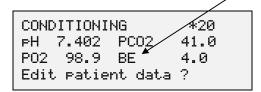
OFF or ON is blinking.

Switch between ON and OFF by pressing $\sqrt{\ }$ or $^{\wedge}$.

Activate the blinking section by pressing YES and 2 measurement reports running will be printed.

Display

This function allows to set the **fourth calculated** value (e. G.: BE in the following display) on the display.



Activate:

Settings? YES
$$9x\sqrt{}$$
 (or $2x\triangle$)

By pressing vor vou can select between the following parameters:

BE	AaDO ₂
cH ⁺	O ₂ cont
O ₂ sat	st.pH
st.HCO ₃	TCO ₂
HCO ₃	BB
BEecf	Shunt
BEact	

Activate your selection by pressing YES. Exit this program by pressing ESC.

Mini Sample

Activate:

Settings? YES $10 \times \sqrt{}$ (or $1 \times \triangle$)

YES

Mini sample?

USER PROGRAMS ON OFF Man. standby o.k. ?

On or OFF is blinking.

By pressing or you can switch between ON and OFF.

Activate the blinking selection by pressing **YES**. and during a capillary measurement the question "Mini sample" will appear on the display. For details, please refer to chapter 4, section "Patient Testing".

9 MAINTENANCE

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9 Maintenance

Introduction

This chapter describes regular maintenance, which helps to assure the liability and measurement quality of the analyzer.

The following maintenance should be performed at the specified intervals. If needed, maintenance can be performed between recommended periods.

NOTE: AVL zero-maintenance electrodes should not be removed for periodic checks. Removal and reinsertion may cause damage.

Decontamination

AVL recommends the following decontamination procedures. Decontamination should be performed in accordance with typical laboratory regulations.

This decontamination should be performed periodically to minimize the risk of infections (incl. hepatitis virus and HIV).

The purpose of this procedure is to minimize the risk when replacing items that were in direct contact with blood.

NOTE: Always wear approved, protective gloves!

The following parts of the device have to be decontaminated:

Daily

- Fill port area
- Keyboard
- Surfaces

As needed

• Sample path

Reagents

NOTE: Use liquid disinfectants only.

Do not use sprays!

AVL Deproteinizer

Composition

Aqueous solution of NaOCl containing ≤ 2.0 % active chlorine.

Hazards identification

Due to the basic and oxidizing character of the reagent ("Deproteinizer") local irritations after contact with eyes, skin or mucous membranes cannot be excluded.

First aid measures

After inhalation: fresh air, drink plenty of water

After skin contact: rinse with plenty of water, remove contaminated clothes

After eye contact: rinse with plenty of water, consult a doctor

If swallowed: drink plenty of water, avoid vomiting, consult a doctor

NOTE: When Deproteinizer is handled and used properly, no ecological problems are to be expected.

Disinfectant

A commercially available alcoholic disinfectant containing aldehyde should be used. Please refer to the product description of the surface disinfectant.

NOTE: Do not use the disinfectant for internal decontamination of the sample path!

Fill port area

For decontamination AVL Deproteinizer is especially recommended. You may also use a commercially available alcoholic disinfectant containing aldehyde.

Sample drip tray

The sample drip tray prevents contamination of the bottle compartment (in case of improper sample introduction). Decontaminate a dirty sample drip tray with a cloth or gauze pad saturated in disinfectant.

Procedure

- 1. Open bottle compartment cover.
- 2. Pull sample drip tray out.
- 3. Clean and decontaminate or replace it.
- 4. Close bottle compartment cover.

Fill port

Decontaminate fill port with a cloth or gauze pad saturated in disinfectant.

Procedure

1. Activate:

User programs ? YES 6x > System test ? YES Electrodes ?YES

- 2. Open flap.
- 3. Decontaminate fill port.
- 4. Close flap.
- 5. Press the key **ESC** twice upon completion of this maintenance procedure.

The system performs a washing/drying procedure and will return to the "READY" screen.

Flap

Decontaminate the inside and outside of the flap with a cloth or gauze pad saturated in disinfectant.

Procedure

1. Activate:

User programs ? YES 6x >>
System test ? YES
Electrodes ?YES

- 2. Open flap.
- 3. Decontaminate the inside and outside of the flap and wait until disinfectant has dried.
- 4. Close flap only after disinfectant has dried completely to avoid damaging the lacquer when reopening the flap.
- 5. Press the key [ESC] twice upon completion of this maintenance procedure.

The system performs a washing/drying procedure and will return to the "READY" screen.

Keyboard

Decontaminate the keyboard with a cloth or gauze pad saturated in disinfectant.

NOTE: Decontaminate with damp cloth only using a disinfectant. Do not use sprays!

Surfaces

Decontaminate all outside surfaces and cover with a cloth or gauze pad saturated in disinfectant.

Sample path / Measuring chamber

Cleaning with AVL Deproteinizer should be performed only when the measuring capillary is contaminated (protein residue) or if components of the measuring path are being replaced.

Such cleaning process basically interferes with the measuring system and the electrodes. They must be conditioned afterwards.

The decontamination agent is introduced via the fill port.

If necessary decontaminate the measuring chamber specially the connecting pieces with a cloth saturated in disinfectant.

Procedure

Activate:

User programs ? YES 3x 🤝 Maintenance ? YES 2x 😺

Cleanin9 ? YES

Perform cleaning according instructions on the display.

NOTE: After reinstalling of the decontaminated electrodes at a later time or a new electrode perform two measurements with a wetting agent (e.g. whole blood) to moisten the system.

Daily Maintenance

Liquid Levels

Check level and expiration date:

- Rinse
- Buffer Type 1
- Buffer Type 2
- pH Reference Solution
- Cleaning Solution

NOTE: Never refill Rinse, Buffer Type 1, Buffer Type 2, Cleaning Solution and pH Reference Solution bottle, always replace. Contamination could occur.

NOTE: If you do not use the prefilled Rinse solution, refill with distilled water only and add one ampoule of Rinse Additive.

If the liquid level is too low, the measuring chamber can become soiled and this can lead to incorrect measuring values.

Waste Bottle

Dispose of or empty and decontaminate the bottle.

NOTE: The waste bottle contains biohazardous substances. Waste liquids should be capped and disposed of according to local regulations.

Printer

Paper: check quantity and replace if necessary.

NOTE: The paper is heat-sensitive on one side only. Please insert correctly.

Correct paper insertion

- 1. Push the paper roll holder slightly to the side and remove the empty roll.
- 2. Insert a new roll of paper.
- 3. Insert the paper in the feeder.
- 4. Press the paper feed (black) button until the paper appears on the outside of the cover.

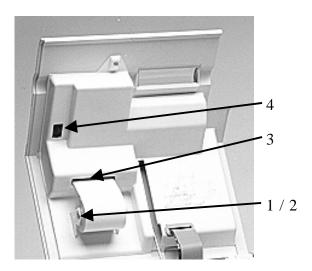


Fig. 9-1: Paper insertion

Gas Supply

Check primary pressure of the precision gas cylinder (min. 10 bar or 150 psi) if necessary replace the gas cylinder.

Check secondary pressure of the precision gas cylinder (min 3 - 4 bar or 45 - 60 psi). If necessary call AVL customer support.

NOTE: To guarantee the specification it is required to use AVL Precision Gases.

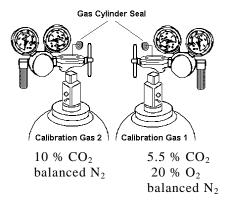


Fig. 9-2: Position of the gas cylinders

Replacing the calibration gas cylinders

- Disconnect the tubes.
- Empty the cylinder completely.
- Release the clasps of the pressure regulator and take off the cylinder.
- Take the empty cylinder out of its holder.
- Dispose of the empty gas cylinder in accordance with local regulations.
- Insert the new cylinder in the holder and secure it.
- Install the pressure regulator on the new gas cylinder (use new gas cylinder seals!).
- Connect the tube with the connector nipple on the rear panel of the AVL COMPACT 3.
- Open the valve of the gas cylinder.

Activate:

User programs ? YES $3 \times \sqrt{}$ Maintenance ? YES $1 \times \sqrt{}$ Gas purge ? YES

NOTE: Do not mix up bottles and tubes.

External Cleaning

Analyzer

Clean analyzer surface with a mild soap solution, if necessary. Do not use strong polishing material.

Fill Port

If soiled, the fill port must be cleaned with a moist cotton swab.

NOTE: The user program "System test" and "Electrodes" for example, must be activated before performing the cleaning cycle so that the analyzer will not detect a measurement (sample) when the flap is opened. This program can only be terminated by pressing ESC and does not have a timeout function.

Quality Control

Perform at least one daily quality control with recommended AVL control material in accordance with your current laboratory regulations.

Weekly Maintenance

pH Reference Electrode

Check the filling of the pH Reference Solution and the permeability.

The permeability of the pH Reference Electrode diaphragm can be tested by touching the electrode tip with a clean dry tissue.

Activate:

Maintenance?

YES

Ref. electrode?

YES

Fill electrode?



USER PROGRAMS Ref. electrode

Check permeability?

Press YES .

Check whether a small droplet of pH Reference Solution forms at the electrode tip. If no droplet is visible, repeat this procedure.

If again no droplet is visible, replace the pH Reference Electrode housing.

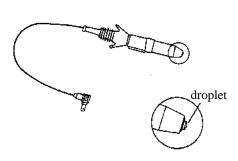


Fig. 9-3: pH Reference Electrode

If the droplet has formed, wipe it off carefully, insert the electrode into the measuring chamber and secure with the clip.

Exit this program by pressing [ESC].

Replace Sample Drip Tray

Remove old drip tray and insert new one.

Every 6 Months

Measuring Chamber Valve

The measuring chamber valve (electromagnetic valve) is located at the far right in the measuring chamber block.

It separates the measuring chamber unit from the sample path, so that syringe samples are not directly inserted in the measuring chamber, but in the bypass.

Procedure

- Pull out the securing clip of the valve and remove the measuring chamber valve from the measuring chamber.
- A cover with a silicone O-ring is located at the tip of the valve.
- Remove the cover from the valve.
- Place a new cover on the valve. Be careful that the silicone O-ring is not pushed out at the front.
- Return the measuring chamber valve into the measuring chamber and secure with clip.
- Close the cover.

Yearly Maintenance

Waste Container

Dispose of the waste container in accordance with local regulations.

Peristaltic Pump Tube

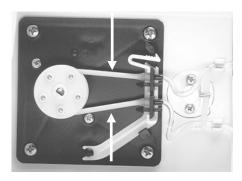


Fig. 9-4: Peristaltic pump tubes

Exchange Pump Tubes

Unlock tension lever and disconnect pump tube. Press tension lever against pump plate and pull the tube plate out of tension lever.

Place the new tube around pump spool and press the tube plate into tension lever until it locks.

Push end of tension lever to the right and slightly against the pump plate until it locks with a click.

NOTE: During the maintenance take care that the pump tubes are not overstretched. Risk of material damage.

Fill Port

NOTE: The user program "System test" and "Electrodes" for example, must be activated before performing the cleaning cycle so that the analyzer will not detect a measurement (sample) when the flap is opened. This program can only be terminated by pressing [ESC] and does not have a timeout function.

Procedure

- Open the flap of the AVL COMPACT 3.
- Grasp the fill port at the lower edge and pull it out.
- Moisten the new fill port with distilled water and press it carefully into its place.
- Close the flap.

Press **ESC** as often as necessary to get READY.

NOTE: During the replacement of the fill port wear protective gloves to avoid any risk, because the fill port can be contaminated.

Preventive Maintenance

Replace all tubes and expendable parts.

Please contact your local AVL customer support.

As needed Pump Spool

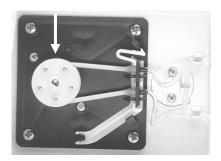


Fig. 9-5: Pump spool

Unlock tension lever and disconnect pump tube. Press tension lever against pump plate and pull the tube plate out of tension lever.

Pull pump spool off and remove clip from motorshaft if necessary. Position spoolhole on motorshaft and turn spool until flat sides match and push spool all the way up the shaft to the pump plate (do not hold shaft).

Place the new tube around pump spool and press the tube plate into tension lever until it locks.

Push end of tension lever to the right and slightly against the pump plate until it locks with a click.

NOTE: During the maintenance take care that the pump tubes are not overstretched. Risk of material damage.

Care and Maintenance of Electrodes

This section describes the care and maintenance required for optimal electrode performance.

Electrode performance is the most important factor influencing the quality of analytical results. Proper care and maintenance is required at regular intervals.

CAUTION!

No electrodes should be removed during calibration or measurement. Please wait until the process has been completed. Maintenance is only necessary when an alarm occurs. Before beginning with maintenance, the user program "System test" and "Electrodes" for example, must be activated. This program can only be terminated by pressing ESC and does not have a timeout function.

NOTE: Before performing electrode maintenance disconnect the electrode cable and remove the electrode clip. Handle the electrodes with care ensuring that electrode tips do not contact any hard surface.

pH / Blood Gas Electrodes

Zero-Maintenance pH / Blood Gas Electrodes

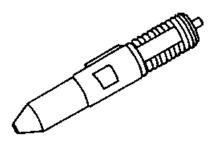


Fig. 9-6: Zero-maintenance pH / Blood Gas Electrodes

The upkeep of the zero-maintenance pH / Blood Gas is limited to regular checks of electrode voltages and the occasional replacement of an electrode whose service life has expired. See attached page for zero-maintenance pH / Blood Gas Electrode information.

NOTE: Zero-maintenance pH / Blood Gas Electrodes do not require any maintenance!

pH Reference Electrode

The pH Reference Electrode is located on the extreme left hand side of the measuring chamber.

To perform maintenance procedures on the pH Reference Electrode, do not interrupt calibration procedures or measurements and leave the analyzer switched on.

Remove the pH Reference Electrode from the measuring chamber block and hold the electrode with the tip downwards. Do not disconnect the tubes.

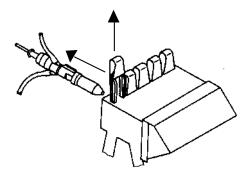


Fig. 9-7: pH Reference Electrode (1)

Filling of the pH Reference Electrode

If the pH Reference Solution in the pH Reference Electrode housing is low, activate:

Maintenance?

YES

Ref. Electrode?

YES

USER PROGRAMS Ref. electrode

Fill electrode ?

Press YES.

This function activates the automatic filling procedure of the pH Reference Electrode housing.

On completion of the filling, the following display appears:

USER PROGRAMS
Ref. electrode

Fill electrode ?

Press when the electrode is filled.

Check permeability of the pH Reference Electrode

The permeability of the pH Reference Electrode diaphragm should be tested. Carefully touch the electrode tip with a clean dry tissue.

USER PROGRAMS Ref. electrode

Check permeability?

Press YES .

Check whether a small droplet of pH Reference Solution forms at the electrode tip. If no droplet is visible, repeat this procedure.

If again no droplet is visible, replace the pH Reference Electrode housing.

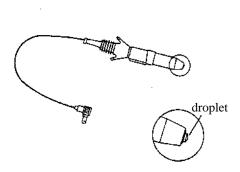


Fig. 9-8: pH Reference Electrode

If the droplet has formed, wipe it off carefully, insert the electrode into the measuring chamber and secure with the clip.

Exit this program by pressing **ESC** .

Replacing the pH Reference Electrode housing

Leave the analyzer switched on. Do not interrupt a calibration or a measurement.

Remove the pH Reference Electrode clip leaving the electrode cable and reference solution tubes attached (see Fig. 9-7).

NOTE: Use gloves while removing the pH Reference Electrode housing. Carefully remove the pH Reference Electrode housing catching any slight spillage of solution in a tissue.

Dispose of the old electrode housing according to applicable safety regulations or procedures.

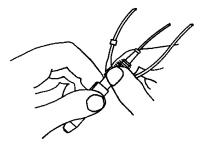


Fig. 9-9: Remove pH Reference Electrode housing

Replace the electrode O-ring if necessary (e.g. if brittle, or worn).

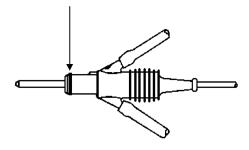


Fig. 9-10: O-ring (pH Reference Electrode)

Remove plastic protection cover and install a new pH Reference Electrode housing.

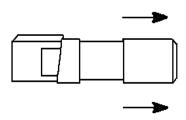


Fig. 9-11: pH Reference Electrode housing

Activate the automatic filling function

User programs?

YES 3x

Maintenance?

Ref. electrode?

Fill electrode?

YES

YES

to fill the new pH Reference Electrode housing and remove air bubbles.

Remembranable pH / Blood Gas Electrodes

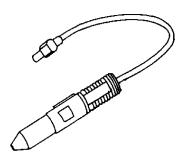


Fig. 9-12: Remembranable pH / Blood Gas Electrode

This electrodes require periodical checks and maintenance like replacement of electrode housing and cleaning.

NOTE: The user program "System test" and "Electrodes" for example, must be activated before performing the cleaning cycle so that the analyzer will not detect a measurement (sample) when the flap is opened. This program can only be terminated by pressing ESC and does not have a timeout function.

Check electrolyte levels of remembranable PCO_2 and PO_2 Electrodes

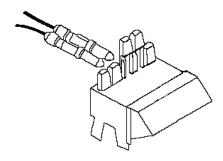


Fig. 9-13: Electrode check (1) - PCO₂ / PO₂ Electrode

Remove the electrodes from the measuring chamber block by lifting the corresponding clips and carefully pulling the electrodes towards the rear.

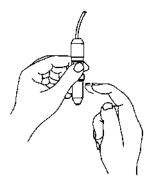


Fig. 9-14: Electrode Check (2) - PCO₂ / PO₂ Electrode

Hold the electrode with the tip downwards. Gently tap it with your finger. If no electrolyte solution is visible regenerate the electrode according to the instructions respectively.

If electrolyte solution is visible, reinstall electrode in its position in the measuring chamber block and secure with the clip.

For details, please refer to chapter 12, section "Care and Maintenance of Remembranable pH / Blood Gas Electrodes".

Cleaning

NOTE: The user program "System test" and "Electrodes" for example, must be activated before performing the cleaning cycle so that the analyzer will not detect a measurement (sample) when the flap is opened. This program can only be terminated by pressing ESC and does not have a timeout function.

Measuring Capillary

If the measuring capillary is heavily soiled, the user has to insert Cleaning Solution like a sample into the fill port.

Activate:

User programs? YES 3x 🗸

Maintenance? YES 2x 😺

Cleaning? [YES]

Perform the cleaning procedure according to the displayed instructions.

10 TROUBLESHOOTING

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10 Troubleshooting

Your AVL COMPACT 3 is equipped with a variety of sensors which control the status of the analyzer.

Operator messages indicating detected system errors or malfunctions will be displayed and printed out.

All error messages are printed on the "Error Report". On this report max. 20 alarms can be listed.

Displayed and Printed Warning

NO Cleaning Solution

This warning indicates that the Cleaning Solution bottle is empty. Check and replace the Cleaning Solution - No system stop!

Displayed and Printed Alarms

There are two kinds of displayed alarms:

- before and during the READY mode,
- during a calibration, conditioning or measurement.

The displayed alarms are:

Electrode Alarms

- PCO2 not calibrated !
- PO2 not calibrated !
- pH not calibrated !
- Check electrodes !

NOTE: Even if one or two of the electrodes are not calibrated, the analyzer will stay limited for the remaining parameter.

Liquid level alarms

- Check Waste !
- No Rinse!
- No REF!

Drift alarms

• No Gas 1 !

Software detection (contact path)

No Buffer 1 !No Buffer 2 !

Various alarms

Check MC temp. !
Check SP temp. !
Meas. path filled !
Check meas. path.!
Check KØ!
No sample !
Service alarms !
Check BARO !

Alarm Causes

- Main Calibration has not been performed accordingly
- Low levels of pH Reference Solution, Buffer Type 1, Buffer Type 2 or Rinse
- Waste container full
- Low flow or low pressure of the external calibration gases
- No vacuum pressure for a wash and dry cycle
- Temperature of the sample inlet path is too high or too low
- Temperature of the measuring chamber is too high or too low
- Soiling

Error Messages and Instructions for Elimination

The following tables contain all possible errors, causes and remedial action.

Error Messages	Possible Cause	Instructions for Elimination
No Sample!	- No sample available	- Insert new sample
	– Capillary-fed sample less than 25 μ1	- Insert new sample (more than 25 μ1). Activate "Micro sample".
	- Sample transport error	- Check pH Reference Electrode
	- Sample path leak	 Check quad ring of the measuring capillary Check O-rings at electrode tips Check membrane of measuring chamber valve Check inlet path Check all accessible tubes (especially peristaltic pump tubing).
	- Wrong sample material	- Insert new sample.
No Buffer 1! No Buffer 2!	Buffer transport errorSample path leak	 Check sample path for leaks Check quad ring of the waste cap Check O-rings at electrode tips Check membrane of measuring chamber valve Check inlet path Check all accessible tubes (especially peristaltic pump tubing).
	- No Buffer Type 1, Buffer Type 2 available	- Replace Buffer Type 1, Buffer Type 2
	- Sample path clogged	- See page 10-9
	- Peristaltic pump failure	- Call AVL customer support!
	- Sample detection contact 1 faulty	- Call AVL customer support!
Check meas. Path!	- Vacuum system leaky	Screw on cap of waste bottle tight.Check quad ring inside the waste cap.
	- Sample path clogged	See page 10-9Activate:Maintenance - Washor
		-Maintenance - Vac. Cleaning
	- If an external waste container is present (optional): The back pressure valve in the cover possibly leaks!	-Check back pressure valve (see chapter 12 – "Appendix", section "Options – External Waste Container")
	- Vacuum pump defective	- Call AVL customer support!

Error Messages	Possible Cause	Instructions for Elimination
No Gas 1!	- Gas cylinder empty	- Check gas pressure. If necessary, replace gas cylinder.
		- Check gas path
	- Gas cylinder valve closed	- Open gas cylinder valve
	- Gas path leaky	- Check gas supply and sample path for leaks
	- PO ₂ Electrode defective	- Check PO ₂ Electrode
Check Waste!	– Dispose or empty the bottle.	- Reinstall and insure the seal tight. Press YES to confirm Waste empty?
	 If an external waste container is present (optional): a waste container with a fill level exceeding 80 % 	- Discard the external waste container exceeding 80 %
No Cleaning	- Bottle empty	- Reinstall a new bottle
Solution!	- pH Reference Electrode empty / check sample path for leaks / sample path clogged	 Check pH Reference Electrode and sample path for tightness
No REF!	- Bottle empty	- Reinstall and insure the seal tight Confirm Fill electrode? by pressing YES. This function activates the automatic filling of the pH Reference Electrode housing
	- Bottle of the pH Reference Electrode leak	– Screw on cap of the bottle tight.
No RINSE	- Bottle empty	 Replace by just filled RINSE bottle or empty bottle completely. Refill with distilled water and add one ampoule Rinse Additive. A wash / dry cycle will be automatically performed.
Meas. path	- Measuring chamber soiled	- Clean measuring chamber
filled!	- Vacuum system leak	- Screw on cap of waste bottle tight
		- Check quad ring inside the Waste cap
	- Sample path clogged	- See page 10-9 - Activate Maintenance - Wash or
	If an automal wasts contained in	Maintenance - Vac. cleaning
	- If an external waste container is present (optional): The back pressure valve in the cover possibly leaks!	-Check back pressure valve (see chapter 12 – "Appendix", section "Options – External Waste Container")
	- Vacuum pump defective	- Call AVL customer support!

Error Messages	Possible Cause	Instructions for Elimination
Check MC- Temperature!	 Module temperature too high because of excessive ambient temperature. 	- Switch off the analyzer - Check ambient temperature (15 32 °C / 59.0 89.6 °F)
Check SP - temperature!	 Module temperature in excess or insufficient because of thermostat failure 	Check Module cables and plugCall AVL customer support!
Check electrodes !		 Print out a calibration report and check status of the analyzer. Check sample path for leaks and clots. Activate: User programs - Maintenance -Wash Change electrodes
		- Perform the corresponding calibration
pН	Voltage too high /too lowExcessive / insufficient slope	 Check pH Reference Electrode. Replace pH Electrode. Perform QC measurement. Repeat measurement. Call AVL customer support!
	pH Electrode plug disconnectedpH Reference Solution	 Connect plug. Check pH Reference Solution cap for leak. Screw cap on tight. Call AVL customer support!
	- Blockage in pH Reference Electrode housing	- Replace pH Reference Electrode housing (see chapter 9, "Maintenance").
	- pH-Reference Electrode housing not full	- Fill up housing with pH Reference Solution (see chapter 9, "Maintenance").
	– pH Electrode soiled	 Clean (see chapter 12, "Care and Maintenance of Remembranable pH / Blood Gas Electrodes") or replace electrode.
	- Measuring chamber temperature	- Call AVL customer support!
	- Buffer Type 1 / Buffer Type 2 contaminated with micro-organism (wrong pH value!)	 Replace Buffer Type 1 / Buffer Type 2 and run a 2-Point Calibration Replace Buffer Type 1 / Buffer Type 2, run a cleaning cycle with Deproteinizer. Rinse the tubes with distilled water for several times, install new Buffer Type 1 / Buffer Type 2 bottle and rinse the tubes with the new Buffer Type 1 / Buffer Type 2 for several times. Perform a main calibration.
	- Tightness of flap	Check fill port.Check wash nipple.
	- Measuring chamber valve	- Check seal adapter.
	– Electrode position	- Check electrode support.

Error Messages	Possible Cause	Instructions for Elimination
PCO ₂	- Voltage too high /too low	Replace PCO₂ Electrode.Perform QC measurement.
	Excessive / insufficient slope.Excessive electrode drift	Repeat measurement.Call AVL customer support.
	 PCO₂ Electrode plug disconnected 	- Connect plug.
	- PCO ₂ Electrode	- Replace electrode housing or electrode.
	- Gas bottle exchanged or empty	- Check gas supply and tubing (see chapter 9, "Maintenance"). Connect properly
	– Leaks	Activate: System Test - Electrodes - Gas 1/Gas 2 internal
		 Check quad ring between preheating tube and measuring chamber.
		 On the left side of the measuring chamber, place a tube reaching into a cup of water and check the water for continuous gas flow.
		- Call AVL customer support.
	- Tightness of the flap	- Check fill port.
		- Check wash nipple.
	- Measuring chamber valve	- Check seal adapter.
	- Electrode position	- Check electrode support.
PO ₂	- Voltage too high /too low	Replace PO₂ Electrode.Perform QC measurement.
	- Excessive / insufficient slope.	Repeat measurement.
	Excessive electrode driftGas bottle exchanged	- Call AVL customer support.
	- PO ₂ Electrode plug disconnected	- Connect plug
	- PO ₂ Electrode	 Replace electrode housing or electrode.
	- Gas bottle exchanged or empty	Check gas supply and tubing (see chapter 9, "Maintenance").Connect properly.
	– Leaks	Activate: System Test - Electrodes - Gas 1/Gas 2 internal
		 Check quad ring between preheating tube and measuring chamber.
		 On the left side of the measuring chamber, place a tube reaching into a cup of water and check the water for continuous gas flow.
		- Call AVL customer support.
	Tieleteres of the floor	– Check fill port.
	- Tightness of the flap	- Check IIII port.

Error Messages	Possible Cause	Instructions for Elimination
PO ₂	- Measuring chamber valve	- Check seal adapter.
	- Electrode position	- Check electrode support.
Service alarms!	- Calibration can not be performed because of alarm(s)	- Remove cause of alarms Activate calibration
Check BARO !	- Characteristic value of Baro is out of range	- Call AVL customer support!

Printed Warnings and Error Messages

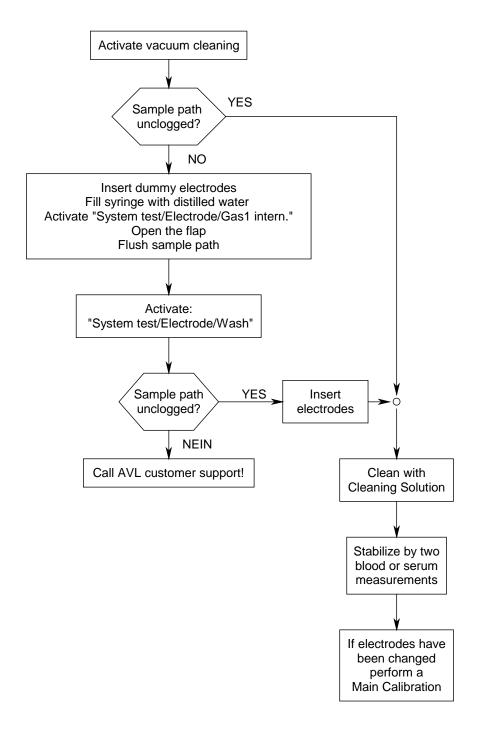
Error Messages	Possible Cause	Instructions for Elimination
Check KØ !	 Sample inlet path soiled Measuring chamber soiled Vacuum system leak 	 Clean measuring chamber Screw Waste cap on tight. Check quad ring of the waste cap.
	 If an external waste container is present (optional): The back pressure valve in the cover possibly leaks! 	-Check back pressure valve (see chapter 12 - "Appendix", section "Options - External Waste Container")
	- Sample path clogged	- See page 10-9.
		- Activate: Maintenance - Wash
		or Maintenance - Vac. cleaning
	- Vacuum pump defective	- Call AVL customer support!
Warnin9	- QC material not defined	-Define QC material
Out of Range	- QCmaterial not correct defined	-Repeat QC measurement
	- QC range(s) not inserted correct	-Enter QC range(s)
		-Repeat QC measurement
	- Sample position not o.k.	-Repeat QC measurement (observe aspiration procedure)
	- Calibration not o.k.	-Check gas pressure and Buffer Type
		- Activate calibration and repeat QC measurement
	- Electrode(s) not o.k.	-For further procedure see "Check Electrodes"

Insufficient Wash and Dry Cycle

Possible Cause	Remedy
Insufficient drying of measuring chamber.	- Extend drying by 10 seconds, see chapter 8, "Settings", section "Extending the Drying Cycle"
Insufficient wetting through use of abrasive cleaning agents (too much Deproteinizer)	- Perform two blood or serum measurements.
Vacuum system leak	 Check waste bottle cap for tight seal. Check quad ring of the waste cap. Check all accessible tubes.
Sample path clogged	- See page 10-9
Vacuum pump failure	- Call AVL customer support!

Clogged Sample Path

Blockage



ATTENTION: To protect against spillage, protective glasses should be worn when attempting to flush a blockage in the sample path with a syringe injection.

Activating a Vacuum Cleaning Cycle

If the sample path or the measuring chamber are clogged, activate a vacuum cleaning cycle.

Activate:

Maintenance?

YES 3×

Vacuum cleanin9?

YES

USER PROGRAMS Vacuum cleanin9 Please wait

At this point, a vacuum cleaning cycle of the sample path and the measuring chamber is performed.

On completion of the cycle the following display will appear:

USER PROGRAMS Maintenance

Vacuum cleanin9 ?

Press [YES] to repeat the process.

Exit this program by pressing **ESC** .

Glass Splinters

NOTE: Risk of contamination!

Under any circumstances wear protective gloves!

NOTE: If there are splinters of glass in the measuring chamber call the AVL customer support.

Should the sample path contain splinters from a broken capillary, remove them as follows:

Open the cover of the analyzer.

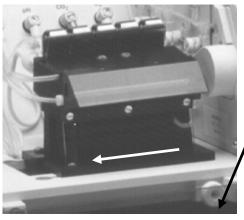


Fig. 10-1: Remove glass splinters (1)

- 1. Loosen the knob that secures the measuring chamber.
- 2. Move the measuring chamber block carefully all the way to the left.

Put a cellulose tissue at the outlet of the preheating tube. Pump the piston of a syringe filled with water to flush the fill tube.

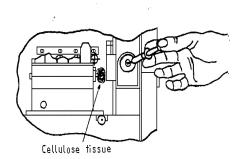


Fig. 10-2: Remove glass splinters (2)

If this does not help, use an appropriate sized stiletto to push the splinters through the pre-induction tube.

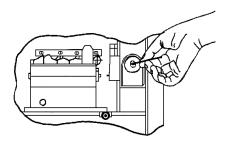


Fig. 10-3: Remove glass splinters (3)

If it was possible to remove the glass splinters, loosen fixing knob (1.), move the measuring chamber block carefully to the right (2.) so that it docks with the preheating tube. When it fits tightly with the preheating tube, secure the measuring chamber by pushing the knob to the correct position.

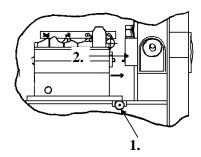


Fig. 10-4: Remove glass splinters (4)

NOTE: Make sure that the quad ring between the measuring chamber and the preheating tube is in correct place to allow for a trouble-free operation cycle.

CH 1 O2 ?

CH 2 CO2 ? CH 3 pH?

CH 4 Barometer ? CH 5 MC Temp. ?

CH 6 SP Temp. ? CH 7 ADC Ref? CH 8 AGND ?

CH 9 K I / K 0 ?

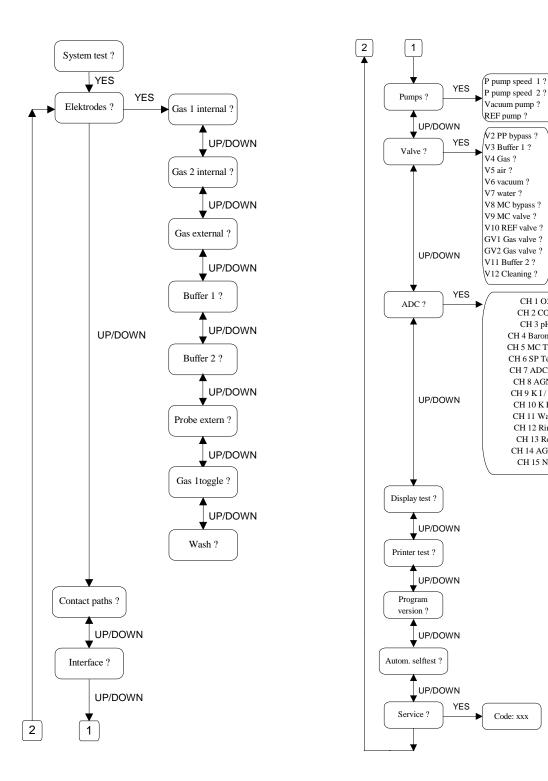
CH 10 K Ref ? CH 11 Waste?

CH 12 Rinse? CH 13 Ref. ? CH 14 AGND ?

CH 15 NC ?

Test Programs

This chapter describes various test programs. Most of these test programs are to be used by AVL customer support only, but some of these test procedures can also be performed by the user.



Activate:

User programs? YES $6x\sqrt{}$ (or $1x\triangle$)

System test? YES

The following system test functions are available:

- Electrodes
- Contact Path *)
- Interfaces *)
- Pumps
- Valves
- ADC *)
- Display
- Printer
- Program Version
- Autom. Selftest
- Service *)

For details, please refer to the **Service Manual** or your local AVL representative.

To abort or to exit this test program press [ESC]. This will put the system into READY mode.

Electrodes

This test program allows the user to check the electrode voltages:

USER PROGRAMS System test

Electrodes ?

Confirm by pressing [YES]. Press \bigvee or \bigwedge to get:

Internal Gas 1

The electrodes are continuously attached with Gas 1 (5.5 % CO_2 , 20 % O_2 , balanced N_2).

Internal Gas 2

The electrodes are continuously attached with Gas 2 (10 % CO_2 , balanced N_2).

^{*)} These functions are for use by AVL customer support.

External gas

Gases to be used:

- gas mixtures (e. g. :calibration gases)
- $-N_2$ gas, to determine the zero point of PO_2 .

Note: Do not use pure O_2 and CO_2 - gas! This could damage your electrodes!

Measuring range: -2500 mV to +2500 mV.

Buffer 1

Measuring range: -970 - +2100 mV Buffer Type 1 measured like a sample.

Buffer 2

Measuring range: -1570 - +1410 mV Buffer Type 2 measured like a sample.

Sample external

To measure an external sample with specified pH, PCO₂ and PO₂ values.

Gas 1 toggle

This function simulates the conditioning during the READY state.

Wash

Like "Wash" in the user program "Maintenance".

Pumps

With this test program the user can check the functionality of the pumps.

USER PROGRAMS System test

Pumps ?

Confirm by pressing [YES].

By pressing vou can now select:

- Peristaltic pump speed 1?
- Peristaltic pump speed 2?
- Vacuum pump?
- KCl pump?

Confirm the selected pump with YES.

USER PROGRAMS Pumps OFF P.Pump speed 1 ?

By pressing YES it is now possible to activate or deactivate the peristaltic pump - speed 1.

Repeat the operation until all speeds were selected.

Exit this test program by pressing [ESC].

Valves

This test is used to check all valves, by opening and closing them.

USER PROGRAMS System test Valves ?

Press YES.

By pressing or or you can now select (see also chapter 12, "Fluidics" diagram):

- V2.....PP bypass?
- V3.....Buffer Type 1?
- V4.....GAS ?
- V5.....Air?
- V6.....Vacuum?
- V7.....Water?
- V8.....MC bypass?
- V9.....MC valve?
- V10...REF valve?
- GV1..Gas valve?
- GV2..Gas valve?
- V11...Buffer Type 2?
- V12...Cleaning?

Confirm the selected valve with • .

USER PROGRAMS
Valves
CLOSE
V2 PP Bypass ?

By pressing • you can now open and close the selected valve.

NOTE: Short opening of gas valve GV1 and GV2 <u>only</u>, to avoid overpressure inside the device.

Repeat this procedure in the same way as often as necessary.

Exit this program by pressing '...

Display Test

This test checks all dots of the display.

USER PROGRAMS System test Display test ?

Press • and you get the following display: This display is correct, when all dots have the same intensity. If not, the LCD-display is faulty.

Printer Test

This test program checks the printer by printing all available Latin characters.

USER PROGRAMS
System test
Printer test ?

Press • and you get the following printout:

THE QUICK BROWN FOX JUMPS OVER THE LAZY DOG the quick brown fox jumps over the lazy dog 0123456789! #%% ()* +, -. /: <=>?[\] $\uparrow\downarrow_{23}$ {|} $\rightarrow\leftarrow$

Exit this program by pressing '

Program Version

This test program shows the program version of the analyzer.

```
USER PROGRAMS
System test
Program version ?
```

Press • .

Example:

```
USER PROGRAMS

COBA 3-ED-X. XX
```

The display shows the actual program version of the AVL COMPACT 3, in the corresponding language versions.

Exit this program by pressing '

Autom. Selftest

This test checks the measuring circuit of the analyzer.

```
USER PROGRAMS
System test
Autom. Selftest?
```

Press • .

```
RAM O. K.
EEPROM O. K.
CLOCK/TIME O. K.
INTERFACE O. K.
EXT. ADC O. K.
INT. ADC O. K.
pH MEASURE O. K.
PO2 MEASURE. O. K.
```

The parameters are always shown in their current condition (o.k. or ERROR).

Other test programs are not described in this chapter.

For details, please refer to the "Service Manual".

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11 Interface

General Description

The AVL COMPACT 3 is fitted (standard) with three serial interfaces for data transfer (COM 1, COM 2, COM 3).

All printed data are automatically sent to each serial interface where PC/Host is activated.

All three ports can be programmed in the user program Settings.

Hardware

Pinning

COM 1 (RS 232)

(9-pin SUBMIN D/F)

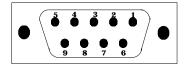


Fig. 11-1: COM 1 / COM 2 - pinning

```
Pin 1 ....... Vcc ....... + 5V
Pin 2 ...... RxD ...... receive data
Pin 3 ...... TxD ...... transmit data
Pin 5 ...... GND ..... signal ground
Pin 9 ..... RI ..... ring indicator
Pin 4, 6-8 ... Not connected
```

COM 2 (RS 232)

```
Pin 2.......RxD......receive data
Pin 3......TxD......transmit data
Pin 4......DTR......data terminal ready
Pin 5......GND.....signal ground
Pin 6......DSR......data set ready
Pin 7.....RTS......request to send
Pin 8.....CTS......clear to send
Pin 1-9.....Not connected
```

COM 3 (RS 232)

(25-pin SUBMIN D / F)

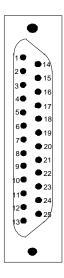


Fig. 11-2: COM 3 - pinning

Pin 2	TxD	transmit data
Pin 3	RxD	receive data
Pin 4	RTS	request to send
Pin 5	CTS	clear to send
Pin 6	DSR	data set ready
Pin 7	GND	signal ground
Pin 20	DTR	data terminal ready
Pin 1, 8-19,	21-25	Not connected

Baud Rate

The baud rate can be set in the user program Settings. Available are:

1200, 2400, 4800, 7200, 9600 baud (9600 default)

Transmission Format

8 Data bit, 1 Stop bit, no Parity

Transmission Report

The data flow is controlled by "Software Handshake" (XON/XOFF) (can also be activated / deactivated in the user program "Settings" - "Interface").

Following control sequences are part of the report and are sent to the interface:

Control sequences	Hex	Ctrl^	Description
STX	\$02	^B	start of text
ETX	\$03	^C	end of text
CR	\$0D	^M	carriage return
LF	\$0A	^J	line feed
XON	\$11	^Q	continue transmission
XOFF	\$13	^S	stop transmission

Reports

The sequence of the report lines can be set in the user program Setti ngs (for details, please refer to chapter 8, "Settings").

```
STX CR LF
     AVL COMPACT 3 CR LF
       BLOOD GAS CR LF
    ACID BASE REPORT CR LF
CR LF
CR LF
Pat. Name: CR LF
Age: 36 F CR LF
Pat. no.: 18 CR LF
Sample: CAPILLARY CR LF
        cap. CR LF
Th, 12-Jul - 96 15: 54 CR LF
CR LF
No.:
             30 CR LF
             724.8 mmHg CR LF
Baro
CR LF
#tHb A 15.2 g/dL CR LF
#Temp 37.0 38.2 À C CR LF
pH 7. 200 7. 184 CR LF PC02 17. 0 17. 0
       17.0 17.9 mmHg CR LF
CR LF
            - 19.3 mmol/l CR LF
BF
            - 19.8 mmol/l CR LF
BEecf
            28.7 mmol/l CR LF
              6.4 mmol/l CR LF
HCO3
CR LF
PO2 126. 3 133. 4 mmHg CR LF
02sat 97.4 % CR LF
CR LF
Op. I D.: CR LF
CR LF
#Input values CR LF
ETX
```

Note

In certain cases the following signs are transmitted instead of measured values or calculated values:

-[*] -	Physiological range is activated - (value within / out of limit)
$\uparrow\uparrow\uparrow\uparrow\uparrow$	Measured value out of range (high limit)
↓↓↓↓↓ <<<<	Measured value out of range (low limit) Electrode signal is out of range (low limit)
>>>>	Electrode signal is out of range (high limit)
*****	No calculation possible (e.g. one electrode not calibrated)
	Electrode not calibrated

Interface Test

Connect Pin 2 and Pin 3 of the standard interface (COM 1) by a wire strap.

Activate:

User programs? YES $1 \times \triangle$ (or $6 \times \bigvee$)

System test? YES 2x√√

Interface? YES

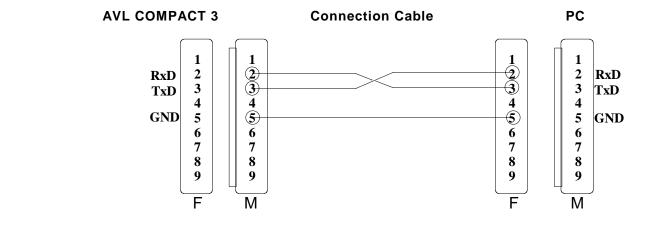
The following display appears:

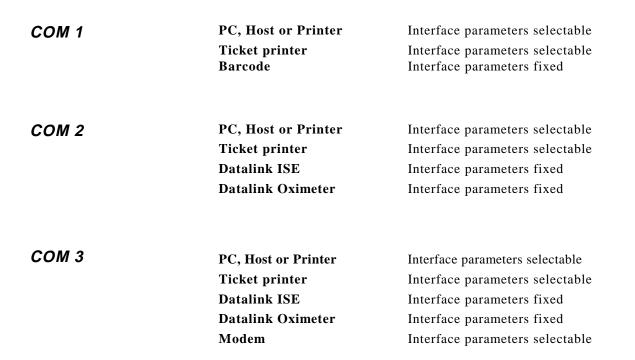
USER PROGRAMS System test Interface o.k.

If the pins are not connected the following display appears:

USER PROGRAMS System test Interface error

Connection Cable AVL COMPACT 3 - PC (Terminal / Printer)





Barcode Scanner

For the AVL COMPACT 3 there is a barcode scanner optionally available. During measurement the patient number can be scanned in.

In addition, the operators identification (OP. ID.) can be scanned in with the barcode scanner, however, only in the READY mode. When the barcode scanner is installed, the password and locking of the analyzer can be activated.



Fig. 11-3: Barcode scanner

NOTE: The active reading unit of the barcode scanner <u>does not</u> light red after being connected.

Specifications

Fix settings

• Baud rate: 1200 Baud

Data bits: 8Stop bit: 1Parity: No

Plug

9-pin SUBMIN D / M (please refer to description of COM 1).

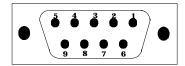


Fig. 11-4: 9-pin SUBMIN D / M

Installation

Connect and fix the barcode scanner to COM 1. For details, please refer to, chapter 8 "Settings", section "Interface".

Types of bar code

All types of bar codes are preset and are put out with a header (PREFIX = STX) and a trailer (SUFFIX = ETX).

Types of Barcode	Presentation
Code 2/5 Interleaved	0123456789
Code 39	0123456789
	ABCDEFGHIJ
Codabar	122 9
Code 128	Code 128

Fig. 11-5: Types of barcode

Datalink

AVL COMPACT 3 to AVL 988-3

The "Datalink" allows the AVL 988-3 to be connected via interface to the AVL COMPACT 3 and convey the respective measurement data. The connection of the different instruments is possible due to the built in interface in the AVL 988-3.

NOTE: Please see that the connection takes place before the instruments are turned on. Use the proper interface cable BV1811 for the connection to the COM 2 of the AVL COMPACT 3 or BV1814 for the connection to the COM 3 of the AVL COMPACT 3.

Description of the Interface (AVL 988-3)

Pinning

The 25-pin interface socket is located on the back of the analyzer above the power supply plug.

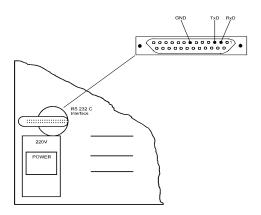


Fig. 11-6: Interface AVL 988-3

Pin 2 TxD transmit data
Pin 3 RxD receive data
Pin 7 GND signal ground

Baud Rate

9600 baud standard.

Transmission Format

8 Data bits, 1 Stop bit, ASCII-code, no Parity.

Controlling the Datalink

The AVL 988-3 sends "Control G" (Hex \$07). The AVL COMPACT 3 responds with "Control F" (Hex \$06).

Signal Level

logical 1 = -12 -3 V logical 0 = +3 +12 V max. cable length: 3m

Software Report

When the Datalink to the AVL COMPACT 3 is activated and the AVL 988-3 has completed measurement, it sends a "BEL" (Hex \$07), to signal the AVL

COMPACT 3 that a datalink report is ready to be transmitted.

The AVL COMPACT 3 answers with a "ACK" (Hex \$06) to receive the datalink report.

If the AVL COMPACT 3 does not answer the "BEL", the AVL 988-3 sends a further signal every 10 seconds.

If this does not occur until the start of a new measurement, "Data not transmitted" will be shown.

If the AVL 988-3 receives an "ACK" from the AVL COMPACT 3, an entire datalink report will be transmitted.

Transfer of Report Data

The single lines of the protocol whose sequence corresponds to the printed protocol, are separated by "CR" (Hex \$07) and "LF" (Hex \$0A).

The first transmitted sign is "Control G", the last transmitted sign is "EOT" (Hex \$04).

Installation of the Units

Connect the AVL COMPACT 3 and the AVL 988-3 with the connecting cable to the provided interfaces.

Turn the analyzers on and wait for the READY mode.

Activating the datalink on the AVL COMPACT 3

User programs?

YES 5x 😾

Settings?

YES 5x 🤝

Interface?

YES

USER PROGRAMS Interface

COM 1 ?

By pressing you may select COM 2 or COM 3.

The following display appears (if you have selected COM 2):

USER PROGRAMS Interface

COM 2 ?

Press [YES] to confirm.

USER PROGRAMS

ON

OFF

COM 2 ?

Select OH and confirm by pressing YES.

USER PROGRAMS

COM 2

Mode ?

Select the interface by pressing \bigvee or \bigwedge and confirm with YES.

USER PROGRAMS Datalink 988

Mode o.k. ?

Select the datalink function by pressing \bigvee or \bigwedge and confirm with \bigvee ES. The datalink is active now.

You may activate the datalink function on COM 3 in the same way.

Activating the datalinks on the AVL 988-3

Activate the service code DIL.

NA - K - CL READY

Press (YES) until following display appears:

INSTRUMENT TEST?

Press (YES) to confirm.

SPECIAL FUNCTIONS?

Press (YES) to confirm.

ADC TEST?

Press (YES).

INTERFACE TEST?

Press (YES).

PROGRAM VERSION?

Press (YES)

SERVICECODE?

Press (YES) to confirm.

SERVICECODE: AAA

Press (YES) to confirm.

Enter code DIL.

The first character is blinking:

With (NO) select the correct character and confirm by pressing (YES) The next character is blinking. Repeat this procedure until the code is correct.

INTERFACE?

Press (YES) to activate the interface..

INTERFACE ON

The analyzer confirms activation for approximately 2 seconds.

The following display appears:

SERVICECODE: ?

Press (YES) until the following display appears:

PROGRAMMING?

Press (YES) to confirm.

Press (NO) until the following display appears:

DATA LINK?

Press (YES) to confirm.

DATA LINK ON

Press (YES) until the following display appears:

NA - K - CL READY

In addition activate the interface of the AVL COMPACT 3. In this data system the measurement values of the AVL 988-3 and the AVL COMPACT 3 will be transferred together and printed with the results of the blood analysis. With the necessary help program, (see Operator's Manual AVL 988-3, chapter 3.4, "Printer Handling") the results can also be printed parallel by the AVL 988-3 if desired.

NOTE: In the case of the parameter combination NA - K - CA, the Ca^{++} value from the data system is calculated from the pH value of the standardized Ca^{++} value from the AVL COMPACT 3, at pH = 7,4 and is printed on the AVL COMPACT 3.

AVL COMPACT 3 to AVL 9180

The "Datalink" allows the AVL 9180 to be connected via interface to the AVL COMPACT 3 and convey the respective measurement data. The connection of the different instruments is possible due to the built in interface in the AVL 9180.

NOTE: Please see that the connection takes place before the instruments are turned on. Use the proper interface cable BV1812 for the connection to the COM 2 of the AVL COMPACT 3 or BV1815 for the connection to the COM 3 of the AVL COMPACT 3.

Description of the Interface (AVL 9180)

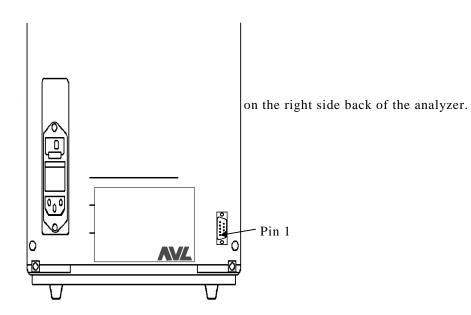


Fig. 11-7: Interface AVL 9180

Pin 2	TxD	transmit data
Pin 3	RxD	receive data
Pin 7	GND	signal ground

Baud Rate

9600 baud standard.

Transmission Format

8 Data bits, 1 Stop bit, ASCII-code, no Parity.

Controlling the Datalink

The AVL 9180 sends "Control G" (Hex \$07). The AVL COMPACT 3 responds with "Control F" (Hex \$06).

Signal Level

logical 1 = -12 -3 V logical 0 = +3 +12 V max. cable length: 3m

Software Report

When the Datalink to the AVL COMPACT 3 is activated and the AVL 9180 has completed measurement, it sends a "BEL" (Hex \$07), to signal the AVL

COMPACT 3 that a datalink report is ready to be transmitted.

The AVL COMPACT 3 answers with a "ACK" (Hex \$06) to receive the datalink report.

If the AVL COMPACT 3 does not answer the "BEL", the AVL 9180 sends a further signal every 10 seconds.

If this does not occur until the start of a new measurement, "Data not transmitted" will be shown.

If the AVL 9180 receives an "ACK" from the AVL COMPACT 3, an entire datalink report will be transmitted.

Transfer of Report Data

The single lines of the protocol whose sequence corresponds to the printed protocol, are separated by "CR" (Hex \$07) and "LF" (Hex \$0A).

The first transmitted sign is "Control G", the last transmitted sign is "EOT" (Hex \$04).

Installation of the Units

Connect the AVL COMPACT 3 and the AVL 9180 with the connecting cable to the provided interfaces.

Turn the analyzers on and wait for the READY mode.

Activating the datalink on the AVL COMPACT 3

User programs? YES 5x 😾

Settings? YES 5x 👽

Interface? YES

USER PROGRAMS Interface

COM 1 ?

By pressing you may select COM 2 or COM 3.

The following display appears (if you have selected COM 2):

USER PROGRAMS Interface

COM 2 ?

Press YES to confirm.

USER PROGRAMS ON OFF COM 2 ?

Select ON and confirm by pressing YES.

USER PROGRAMS COM 2 Mode ?

Select the interface by pressing \bigvee or \bigwedge and confirm with YES.

USER PROGRAMS Datalink 988 Mode o.k. ?

Select the datalink function by pressing \bigvee or \bigwedge and confirm with \bigvee ES. The datalink is active now.

You may activate the datalink function on COM 3 in the same way.

Activating the datalinks on the AVL 9180

Activate the service code KEY.

NA - K - CL READY

Press No.

PRINT FUNCTIONS?

Press No.

QC/STANDARD/DIALYSAT URINE SAMPLE?

Press No.

DAILY MAINTENANCE?

Press No.

OPERATOR FUNCTIONS?

Press No.

PROGRAM INSTRUMENT?

Press YES.

Enter Code: AAA?

Enter code KEY.

The first character is blinking:

With **No** select the correct character and confirm by pressing **YES**.

The next character is blinking. Repeat this procedure until the code is correct.

Program QC Level 1 Ranges ?

Press No.

Program QC Level 2 Ranges ?

Press No.

Program QC Level 3 Ranges ?

Press No.

Program
Normal Ranges ?

Press No.

Program Corr. Factors ?

Press No.

Program Bicarb. Corr. Factors?

Press No.

Program Acetate. Corr. Factors?

Press No.

Program Printer Setup?

Press No.

Program Interface?

Press YES.

Activate Data Link?

Press **YES** to activate the data link between AVL 9180 and AVL COMPACT 3.

In addition activate the interface of the AVL COMPACT 3.

In this data system the measurement values of the AVL 9180 and the AVL COMPACT 3 will be transferred together and printed with the results of the blood analysis.

NOTE: In the case of the parameter combination NA - K - CA, the Ca^{++} value from the data system is calculated from the pH value of the standardized Ca^{++} value from the AVL COMPACT 3, at pH = 7,4 and is printed on the AVL COMPACT 3.

After completion of data link the following display appears on the AVL 9180:

Remain in Program Func.?

Press No, the analyzer returns to READY.

AVL COMPACT 3 to AVL 912

"Datalink" can be used to connect the AVL 912 and the AVL COMPACT 3 and convey the respective measurement data.

NOTE: Please make sure that the proper connections are made prior to turning the instruments on.

Use the proper interface cable BV1810 for the connection to the COM 2 of the AVL COMPACT 3 or BV1813 for the connection to the COM 3 of the AVL COMPACT 3.

NOTE: In the mode "Microsample" the measurement of all desired parameters has to be finished before starting a measurement on the AVL 912!

Description of the Interface

Pin Occupancy

The 9-pin SUBMIN D / F interface socket is located on the back of the analyzer above the power supply plug.

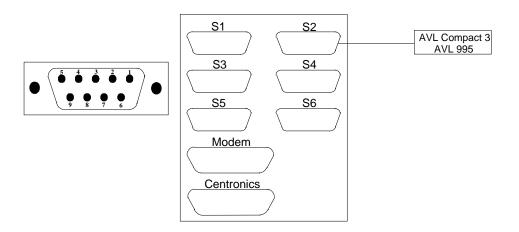


Fig. 11-8: Interface AVL 912

Pin	2	TxD	transmit data
Pin	3	RxD	receive data
Pin	7	GND	signal Ground

Baud Rate

7200 baud

Transmission Format

7 Data bits, 2 stop bits, even Parity

Software Report

Control	Hex	^	Description
ACK	\$06	^F	acknowledge
ETX	\$03	^C	end of text
CR	\$0D	^M	carriage return
LF	\$0A	^ J	line feed
BEL	\$07	^G	bell

When the Datalink to the AVL COMPACT 3 is activated and the AVL 912 has completed measurement, it sends a "DC2" (Hex \$12) and a "ETX" (Hex \$03), to signal the AVL COMPACT 3 that a datalink report is ready to be transmitted.

The AVL COMPACT 3 answers with a "BEL" (Hex \$07) to receive the datalink report.

If the AVL 912 does not receive the "BEL" from the AVL COMPACT 3 an entire datalink report will be transmitted.

Installation

Connect the AVL COMPACT 3 and the AVL 912 with the connecting cable to the provided interfaces.

Turn the analyzers on and wait for the READY mode.

Activating the Datalinks on the AVL COMPACT 3

User programs?

Settings?

Interface?

YES 5x

YES 5x

YES

USER PROGRAMS Interface COM 1 ?

By pressing you may select COM 2 or COM 3.

The following display appears (if you have selected COM 2):

USER PROGRAMS Interface COM 2 ?

Press [YES] to confirm.

USER PROGRAMS ON OFF COM 2 ?

Select ON and confirm by pressing YES.

USER PROGRAMS COM 2 Mode ?

Select the interface by pressing vor and confirm with VES.

USER PROGRAMS Datalink Mode o.k. ?

Select the datalink function by pressing \bigvee or \bigwedge and confirm with \bigvee ES. The datalink is active now.

You may activate the datalink function on COM 3 in the same way.

Activating the Datalinks on the AVL 912

There is no activation of the datalink function necessary at the AVL 912. The datalink function is automatically activated.

Telelink

A modem and PC are needed to perform tele-maintenance by AVL customer support.

This option can only be performed with COM 3.

Technical Specifications

- RS232 Interface
- 8 Data bits, 1 Stop bit, no Parity, 1200 baud (default)
- NONE / HARDWARE Handshake
- HW Handshake → CTS/DTR
- ANSI terminal standard

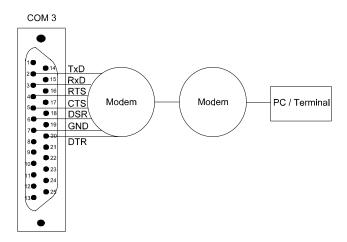


Fig. 11-9: Telelink

Product Description

- After login by Telelink all AVL COMPACT 3 display and printer information is transmitted to the ANSI terminal.
- Now the AVL COMPACT 3 display is deactivated ("TELELINK" is on the AVL COMPACT 3 display).
- The AVL COMPACT 3 display information is transmitted to the ANSI terminal, the AVL COMPACT 3 printer-information is also transferred to the ANSI terminal.
- The buttons on the AVL COMPACT 3 are simulated via terminal commands, the buttons on the AVL COMPACT 3 are deactivated.
- General activation/deactivation will be performed in the user program "Settings".
- Default values are deactivated.

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12 Appendix

Specification of the Analyzer

Measured Value		Displayed Range	Resolution
PO ₂		-10 742 mmHg	0.1 mmHg
PCO_2		4 200 mmHg	0.1 mmHg
pН		6.000 - 8.000	0.001
Barometer		300 800 mmHg	0.1 mmHg
		375 1058 mbar	0.1 mbar
Normal Sample (> 55 µl), Mini (limitation of volume by conta Microsample (25 - 55 µl)		Specification for whole blood	Stand. Deviation
PO_2		0.0 143 mmHg	≤ 1.2 mmHg
. 0 2		143 742 mmHg	1.2 15.0 mmHg
PCO ₂		4.0 40 mmHg	0.2 0.8 mmHg
. 002		40 200 mmHg	0.8 4.0 mmHg
pН		6.000 - 8.000	≤ 0.005
Input Value		Range (conv.) *	Default
Patient temperature		14 44 °C,	37 °C
Total Hemoglobin	tHb	$1\;\;26\;g/dL$	15 g/dL
		0.716.1 mmol/l;	9.3 mmol/l
Hamaalahin tuna		10260 g/l adult / fetal	150 g/l
Hemoglobin type	P50 adult	15 40 mmHg	adult 26.7 mmHg
	P50 addit	10 40 mmHg	21.5 mmHg
Fraction of Inspired Oxygen	FIO_2	0.11 0.99	0.21
Respiratory Quotient	RQ	0.71 1.99	0.84
Patient number		10 digits max.	0.01
Patient age		0 99 years	
Patient sex		male / female	
*SI units are also available.			
Calculated Values		Range	
Actual bicarbonate	HCO ₃ (HCO3)	1 100 mmol/l	
Total CO ₂	$ctCO_2$ (TCO2)	1100 mmol/l	
Base excess in vitro	BE	-40+40 mmol/l	
Base excess in vitro at actual			
oxygen saturation	BEact	-40+40 mmol/l	

	Range
BEecf	-40 +40 mmol/l
BB	1 100 mmol/l
pH _{st} (st. pH)	6.5 8.0
HCO _{3st} (st.HCO3)	1 100 mmol/l
SO_2 (O2sat)	0100 %
ctO_2 (O2cont)	0 56 vol%
$AaDO_2$	0742 mmHg
cH^+	10 1000 nmol/l
$AaDO_2$	0742 mmHg
niCa _{pH=7.4}	0.1 6.0 mmol/l
PO_2^{t}	0742 mmHg
PCO_2^{t}	0200 mmHg
pH^t	68
Shunt	0100 %
20 % O ₂ , 5.5 % CO ₂ ,	balanced N ₂ (+/- 0.03 % absolute)
10 % CO ₂ , balanced N	
3 - 4 bar (43.5 - 58 psi)	
blood, (serum, plasma	a - for pH only)
AVL approved quality	
syringe, capillary, Microsampler	
	e) n capillary mode, limitation by contact path)
25-55 µl (microsample	
SI, conventional	
Sample rate (capillary mode) up to 32 samples per hour	
up to 32 samples per 1 (1P recalibration);	hour with interruption of conditioning
	BB pH _{st} (st. pH) HCO _{3st} (st.HCO ₃) SO ₂ (O2sat) ctO ₂ (O2cont) AaDO ₂ cH ⁺ AaDO ₂ niCa pH=7.4 PO ₂ ^t PCO ₂ ^t pH ^t Shunt built-in thermal printo 2x RS 232, 9-pin SUI 1x RS 232, 25-pin SU 1x RS 232, 25-pin SU 3 - 4 bar (43.5 - 58 ps blood, (serum, plasma AVL approved quality syringe, capillary, Mi ≥55 μ1 (capillary mod 60 μ1 (Mini sample i 25-55 μ1 (microsample)

Temperature / Humidity

Ambient temperature	15 °C - 32 °C, (59 °F89.6 °F)
Measuring chamber temperature	37 °C ± 0.1 °C, 98.6 °F ± 0.18 °F
Relative humidity	20 - 90 %

Electrical Supply

Voltage range	100 - 240 V AC, self adapting
Frequency	50 - 60 Hz
Power consumption (max.)	typical 65 VA,

Classification

Safety category I

Instrument type B (following ÖVE - MG/EN 60 601-1, IEC 601-1)

Operation type For continuous operation

Protective system IP20

Ex - protection The device is not specified for operation inside explosion hazardous

max. 110 VA (depending on actual operating mode)

areas.

Dimensions / Weight

Width		(13.4 inch)
Depth	31.5 cm	(12.4 inch)
Height	34 cm	(13.4 inch)
Weight	13.0 kg	(28.7 pounds)

Acoustic Noise Level

standby	28 dbA
ready	28 dbA
wash/dry	60 dbA
measurement	43 dbA

Test Certificates

<u>۔ . . ت</u>

OVE	tested according to the standard EN60601-1/1991
TÜV	tested according to the standard EN61010-1/1993, 1995

NOTE: According to the TÜV standard only TÜV tested pressure regulator and gas cylinder are allowed to be used!

CSA tested according to the standard C22.2 Nr.151-M1986

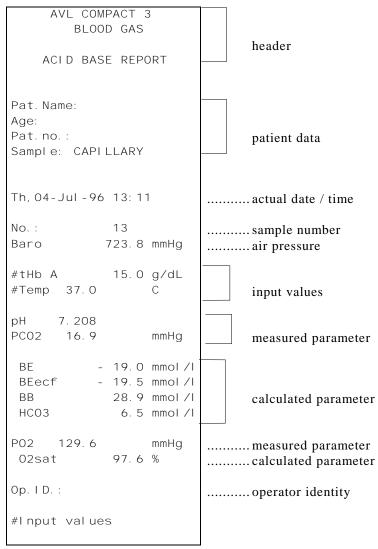
CE-Conformity The analyzer corresponds to the directive 89/336/EWG

(EMC-directives), tested according to the generic standard EN50081-1 and EN00081-2, as well as 73/23/EWG (Low Voltage Directive with addition 93/68/EWG), tested according to EN61010-1, and is allowed to be labeled

with the CE-marking.

Description of Various Reports

Standard Measurement Report

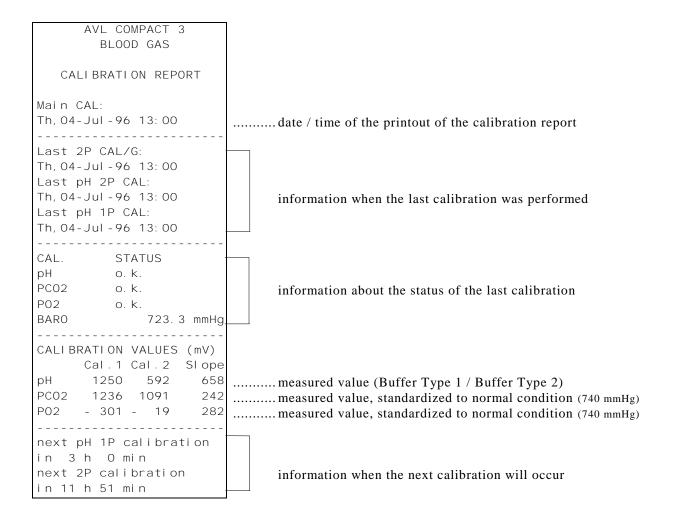


Report with Patient-Related Data

AVL COMPACT 3 BLOOD GAS	
ACID BASE REPORT	For example:
Pat. Name: Age: 36 F Pat. no.: 18 Sample: CAPILLARY cap.	Age:
Th, 04-Jul - 96 15: 54	Day of the week, date, month, year, hour, minute
No.: 30 Baro 724.8 mmHg	No.:
#tHb A 15.2 g/dL #Temp 37.0 38.2 A C pH 7.200 7.184 PC02 17.0 17.9 mmHg	tHbA:total hemoglobin [g/dL] (A = adult) Temp:patient temperature [°C] - 37.0 °C standard temp. 38.2 °C patient related temperature pH:value at standard temperature / value at 38.2 °C PCO2:value [mmHg] at 37 °C / value at 38.2 °C
BE - 19.3 mmol/l BEecf - 19.8 mmol/l BB 28.7 mmol/l HCO3 6.4 mmol/l	BEbase excess [mmol/l] BEecfbase excess of extra cellular fluid BBbuffer base HCO3actual bicarbonate
P02 126.3 133.4 mmHg 02sat 97.4 %	PO2:value [mmHg] at standard temp. / value at 38.2 °C 02satoxygen saturation
Op. I D. :	
#Input values	
	Other possible characters:

↑↑↑↑↑measured value out of range (high limit)
↓↓↓↓↓measured value out of range (low limit)
<>< <amplifier (low="" is="" limit)<="" of="" out="" range="" td=""></amplifier>
>>>>amplifier is out of range (high limit)
******no calculation is possible
mot calibrated
MC Temp measuring chamber temperature over 37 $^{\circ}\text{C}$ - the analyzer is still ready for measurements, but the values are no longer within the specifications

Calibration Report



Calibration Alarms Printed out on the Calibration Report

VA	LUES	A L A R M S					
	PRINTOUT	RANGE	REPRO	DRIFT	NO GAS		
pH Buffer 1	pH B1	- 970 2100	> ± 10 mV	> ± 0.024			
pH Buffer 2	pH B2	- 1570 1410	$> \pm 15 \text{ mV}$				
pH slope	pH slp	430 740					
PCO ₂ Gas1	PCO2 Gas 1	- 300 1500		>3 mmHg (appr20mV)	Drift > 6 mmHg		
PCO ₂ Gas 2	PCO2 Gas 2	- 120 1400					
PCO ₂ slope	PCO2 slp	190 286					
PO ₂ Gas 1	PO2 Gas 1	- 640 60		>5 mmHg			
PO ₂ Gas 2	PO2 Gas 2	- 71 62					
PO ₂ slope	PO2 slp	+ 120 + 560					

Printout	Description
RANGE	the electrode voltage is out of range
REPRO	less reproducibility between two measurements (e.g. 2 x Buffer Type 1 aspirated)
DRIFT	less reproducibility between two calibrations
NO GAS	shows a drift, typical for low CO ₂ (e.g. system leak, gas cylinders empty)
NO BUFFER	No buffer solution available.

Other Printed Alarm

POWER FAIL

Indicates that there was no power for more than just a few seconds (e.g. switch off).

If the power fail lasted less than 20 minutes - the analyzer is still READY after switching on the analyzer.

If the power fail lasted longer than 20 minutes, a main

calibration is required after switching on the analyzer.

System Status Report

The system status report contains of a calibration report and the following additional system information:

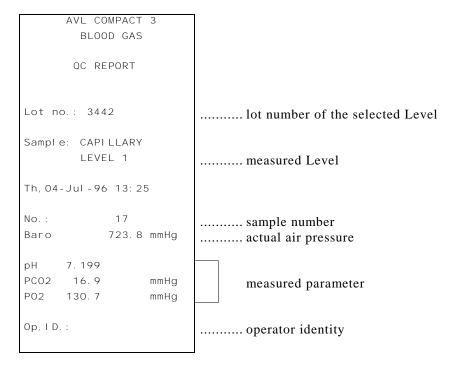
```
AVL COMPACT 3
        BLOOD GAS
 SYSTEM STATUS REPORT
COBA3-XX-XXX
                          ..... the actual program version / language is indicated
Calibration report, see
page 12-6!
_____
         from
                to
рН В1
         - 970 2100 mV
         - 10
REPRO
                10 mV
DRIFT
        -0.024 0.024 pH
рН В2
         -1570 1410 mV
REPR0
        - 15
                15 mV
pH SIp
           430
                740 mV
PC02 Gas1 300 1500 mV
                                limits of the calibration values
DRIFT mmHg-3.0
                3.0
PC02 Gas2 120 1400 mV
                286 mV
PCO2 SIp
           190
P02 Gas 1 - 640 - 60 mV
DRIFT mmHg-5.0 5.0
P02 Gas 2 - 71
                62 mV
          120 560 mV
PO2 SIp
Electrode values(mV):
        pH PC02 P02
        588
В2
                          ..... Buffer Type 2
        595
В2
                          ..... Buffer Type 2
REPR0
         6
                          ..... reproducibility of the values (pH)
В1
       1245
                          ..... Buffer Type 1
В1
       1251
                          ..... Buffer Type 1
       1249
                          ..... Buffer Type 1
REPRO -
          2
                          ..... reproducibility of the values (pH)
DRIFT
            рН
                          ..... drift of the pH values
             1242 - 302
Gas 1
                          ..... actual Gas 1 value (mV)
DRIFT mmHg - 0.1 0.5
                          ...... drift of the Gas 1 value (mmHg)
Gas 2
             1091 - 19
                          ..... actual Gas 2 value (mV)
DRIFT-S
               %
                     0%
                          ...... drift of the slope; value earliest after two calibrations
Sample counter: 000470
______
Conversion factors:
      SLOPE INTERCEPT
P02
      1.00
             0.0
PC02 1.00
             0 0
     1.000
             0.000
```

Error Report

On this report all appeared errors (maximal up to 20 / report) are printed. Each further error will be printed at the end of this report, at which the first error of the report will be deleted.

AVL COMPACT 3 BLOOD GAS ERROR REPORT Printout: Th, 04-Jul - 96 11: 49 Mo, 01-Jul - 96 13: 24 No GAS 1 ! Mo, 01-Jul - 96 13: 24 Check electrodes! Mo, 01-Jul - 96 13: 30 PCO2 NOT CALIBRATED Mo, 01-Jul - 96 13: 45 No sample! Mo, 01-Jul - 96 14: 13 ph NOT CALIBRATED Mo, 01-Jul - 96 15: 50 pH NOT CALIBRATED Mo, 01-Jul - 96 15: 57 ph NOT CALIBRATED Mo, 01-Jul - 96 19: 14 POWERFAI L Mo, 01-Jul - 96 19: 32 POWERFAI L Mo, 01-Jul - 96 19: 36 No sample! Mo, 01-Jul - 96 19: 40 No sample! Mo, 01-Jul - 96 19: 47 No sample! Mo, 01-Jul - 96 19: 56 No sample! Mo, 01-Jul - 96 19: 59 No sample! Mo, 01-Jul - 96 20: 01 No sample! Mo, 01-Jul - 96 20: 04 No sample! Mo, 01-Jul - 96 20: 57 POWERFAIL Th, 04-Jul - 96 02: 37 No Rinse! Th, 04-Jul - 96 11: 39 POWERFALL! Th, 04-Jul - 96 11: 47 POWERFALL !

QC Measurement Report



If the function "Multirule" is activated, the following notes can be printed on the report:

- OUT OF CONTROL
- WARNING

These notes allow to detect as early as possible random or systematic errors of the instrument and of the operation.

For details, please refer to section "AVL Multirule QC Procedure", page 12-15.

QC Statistics Report

Example: Level 1, PCO₂

```
AVL COMPACT 3
          BLOOD GAS
 QC - STATISTICS REPORT
Th, 04-Jul - 96 13: 57
SN: 00260
LEVEL 1 PC02
                                  ..... measured Level / parameter
Range: 128 - 144
                                  .....target range (\overline{X} - 2s \text{ to } \overline{X} + 2s)
                                                                                                 according
                                       mean value (\overline{X}) = 136; standard deviation (s) = 4
                                                                                                 to the
Lot no.: 3442
                                  .....lot number of the measured Level
                                                                                                 insert
Expiration date: 07 95
M :
       137.503 mmHg
                                  .....M - mean value of the stored values
SD:
         5.568
                                  .....SD - standard deviation of the stored values
CV:
         4.0 %
                                  .....CV [\%] = SD \times 100 / M
        130.7
                   04 - Jul
                                  .....number ... measured value ... date of the measurement
                   04 - Jul
  3:
        132.0
  4:
        133.7
                   04 - Jul
  5:
        137.5
                   04 - Jul
  6:
        140.6
                   04 - Jul
        142.6
                   04 - Jul
                   04 - Jul
  8:
        145.3
                   04 - Jul
        157.0
                                   Graphic chart of measured values concerning mean value (\overline{\chi})
                                   and standard deviation (s) in accordance with the insert:
                                  ..... mean value (\overline{X}) \pm 1 (2,3) standard deviation (s)
                                  .....1. value is 2s below the mean value
                                  .....2. value is 1s below the mean value
                                  .....3. value is 1s below the mean value
                                                                                                  Levey-
                                  .....4. value is 1s more than the mean value
                                                                                                  Jennings-
                                  .....5. value is 2s more than the mean value
                                                                                                  diagram
                                  .....6. value is 2s more than the mean value
                                  .....7. value is 3s more than the mean value
                                  .....8. the measured value is out of the target range
                                  * .....the measured value is within the target range
                                  x....the measured value is out of the target range
```

If the AVL Multirules are ON the following characters are printed at the end of the report:

x out of control

* o.k.

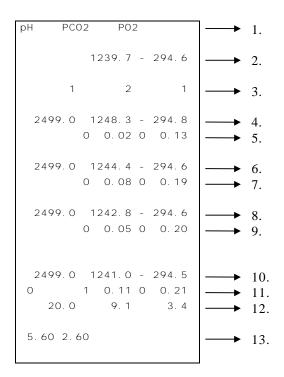
o warning

For activation of the AVL Multirules, please refer to chapter 8, Settings", section, "AVL Multirule".

For details about the function "AVL Multirule", please refer to page 12-15, "Parameters and Equations".

mV Report

NOTE: Necessary only for AVL customer support!



Lines:

- 1. name of the electrodes
- 2. mean value of Gas 1 value
- 3. describes the shape of the curve for the tendency to set (more than one number means an extension of the measuring time).
 - 0 strict
 - 1 monotonic flat
 - 2 monotonic
 - 3 not monotonic
- 4., 6., 8. sample value [mV]
- 5., 7., 9. number of artifacts (0) \pm standard deviation
- 10. predetermined value (calculation of the sample values [mV])
- 11. kind of predetermination (0) and standard deviation of the predetermination.

shape of the curve:

- 0 flat
- 1 passing over to flat
- 2 steep
- 9 not exponential
- 12. Tau tendency to set of the measuring signal
- 13. time for filling during measurements / buffer calibration

Datalink

This printout shows the results of the AVL COMPACT 3 and with datalink connected devices.

```
AVL COMPACT 3
       BLOOD GAS
    ACID BASE REPORT
Pat. Name:
Age:
Pat. No.:
Sample: CAPILLARY
Th, 04-Jul - 96 13: 11
No.:
           1.3
Baro
          723.8 mmHg
#tHb A
           15.0 g/dL
#Temp 37.0
                ÀС
pH 7. 208
PC02 16.9
                 mmHg
         - 19.0 mmol/l
BE
 BEecf
          - 19.5 mmol/l
 BB
            28.9 mmol/l
HCO3
            6.5 mmol/l
P02 129.6
                 mmHg
      OXI DATA ***
            0.0 %
    SHb
   02Hb
             4.3 %
KAP tHb
            22.1 G/dL
   02SAT
            72.9 %
    02CT
             1.3 vol %
    COHb
            93.2 %
   MetHb
             0.8 %
    HHb
             1.6 %
   02KAP
             1.8 vol %
*** ISE DATA
                 * * *
** AVL 988-3 **
ELECTROLYTE ISE
* NA-K -CA
04-JUL-96 11: 46
NAME: . . . . . . . . . . . . . . . .
SAMPLE: SERUM
NO. 157
NA= 105. OMMOL/L
K= 1.96MMOL/L
CA(pH 7.4) = 2.56MMOL/L
#Input values
```

results of the AVL COMPACT 3 measurement

results of the CO-Oximeter connected with AVL COMPACT 3

results of the ISE analyzer connected with AVL COMPACT 3

Parameters and Equations

AVL Multirule QC Procedure

AVL recommends QC measurement is performed at least once a day, to evaluate the reliability and performance of the analyzer. The QC Software of the AVL COMPACT 3 therefore uses the AVL Multirule procedure - a special QC concept - which is based on the Westgard-Rules. This procedure allows to detect as early as possible random or systematic errors of the instrument and of the operation.

NOTE: The AVL Multirule procedure for AVL COMPACT 3 can be used only in connection with a QC material, recommended by AVL e.g. AVL CONFITEST.

Overview of AVL Multirules

Valid for the measured parameters PO2, PCO2 and pH.

Run: Measurement within two 2-Point Calibrations.

 \overline{X} : Mean value

Within run: Observation period between two 2-Point Calibrations

Rule	Interpretation	Remark
$1_{2\sigma}$	QC value exceeds $\overline{x} \pm 2 \sigma$ limits	Warning
$1_{3\sigma}$	QC value exceeds $\overline{x} \pm 3 \sigma$ limits	Out of Control
$(2 \text{ of } 3)_{2\sigma}$	Two of three QC values exceed the same	Out of Control
	$\overline{X} + 2 \sigma \text{ or } \overline{X} - 2 \sigma \text{ limit}$	

Across run: Observation period more than three 2 point calibrations

Rule	Interpretation	Remark
$2_{2\sigma}$	Two QC values of one level exceed the same $\overline{X} + 2 \sigma$ or $\overline{X} - 2 \sigma$ limit (same side of deviation). Observation period is two runs.	Out of Control
$6_{1\sigma}$	Six QC values (level I, II and III) exceed the same $\overline{X} + 1 \sigma$ or $\overline{X} - 1 \sigma$ limit.	Out of Control
	Observation period is three runs.	
$9\overline{X}$	Nine QC values (level I, II and III) fall on the same side of the \overline{X} .	Out of Control
	Observation period is five runs.	

Table 1: Overview of AVL Multirules

All rules shown in Table 1 are implemented in the AVL COMPACT 3 QC software and are used for every QC measurement, if the function "AVL Multirule" was activated in the user program "Settings".

NOTE:

- The operator has to activate the AVL Multirule procedure (see chapter 8)
- Use only one QC material of one lot (e.g. AVL CONFITEST), do not mix the QC materials.
- Single measurements are stored automatically if the results of all three
 measurements are within the range \$\overline{\chi}\$. ±3 σ. Otherwise the operator has to
 decide whether the results should be stored or not.
- For each new lot of QC material, the user has to enter the corresponding mean values and standard deviations (see chapter 5) according to the package insert sheet.
- When using actual QC data to re-define the mean values and standard deviations, AVL recommends making more than 20 QC measurements for calculating these new target values. This new mean value and standard deviation influence the Levey-Jennings-Diagram and the results of the Multirule analysis, but they do not influence the stored data.
- A maximum of 34 single measurements are stored.
- The patient measurement data will not be influenced in any way by using this AVL Multirule procedure.
- The lab supervisor or the physician is responsible to decide if sample data marked with "Warning" or "Out of Control" should be rejected or not, and which further actions have to take place.

Bibliography:

- Elsa F. Quam BS, Lorene K. Haessig BS, Marlene J. Koch BS:
 A Comprehensive Statistical Quality Control Program for Blood Gas Analyzers.
 Journal of Medical Technology 2:1 January 1985
- 2. James O. Westgard, et al:

 A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry.

 Clinical Chemistry, Vol. 27, No.3, 1981

Shunt Parameter

The Shunt parameter is a measure for the direct mixture of venous blood in the oxygenated circulatory system. The Shunt parameter gives the short circuit volume relating to the total volume (% - value).

Activate:

```
User programs?5x "Settings?8x " (or 2x ')Report?2x "
```

Select the "Individual report editor" and the "Shunt" parameter. If the Shunt parameter was selected the Shunt should always be calculated and given. The Shunt volume can be determined with one sample, however better with two sample measurements. The SI and the conventional unit for Shunt volume is %.

The output on the report can appear as follows:

AVL COMPACT 3 BLOOD GAS
ACID BASE REPORT
Pat. Name: Age: Pat. no.: Sample: CAPILLARY ven.
Standard Measurement Report, see page 12-4!
Shunt 7.4 % with Samp.: 46 / 47
Op. I D. :
#Input values

The first number (46) is the sample number of the arterial sample, the second number (47) is the sample number of the venous sample.

The second number is deleted when the Shunt volume is only determined with one measurement.

Requirements

The Shunt volume can only be calculated at a patient temperature not 37 °C. By deviating from the temperature "****" will be indicated on the report. Principally there are four possibilities to calculate the Shunt volume.

- 1. sample type must be arterial or capillary;
- 2. sample type must be arterial or capillary **and** venous, but the sequence is not important;
- 3. such as 1., but in datalink to CO-Oximeter;
- 4. such as 2., but in datalink to CO-Oximeter.

Shunt calculation with one measurement (with or without oximeter)

- The measurement values pH, PCO_2 and PO_2 are valid.
- The sample type must be arterial or capillary

NOTE: It may not be venous!.

Shunt calculation with two measurements (with or without oximeter)

- The measurement values pH, PCO_2 and PO_2 are valid.
- The sample type **must be arterial or capillary**, the previous measurement **must be venous** or vice versa.
- The patient data (Pat. number, age, sex) and the patient parameters (Pat. temperature, tHb, a/f FIO_2 , RQ, P_{50}) of the two measurements must conform.
- Both measurements must have been successfully performed with the oximeter. Otherwise all oximeter-data is canceled and the procedure takes place as without datalink.

NOTES FOR OPERATION: At air breathing ($FIO_2 = 0.21$) it is better to measure only with an AVL COMPACT 3, without datalink. At oxygen breathing ($FIO_2 > 0.4$) a measurement with datalink is better.

Bibliography:

- 1. H. Breuer, H- Büttner, D. Stamm (Hrsg.), O. Müller-Plathe: Säure-Basen-Haushalt und Blutgase, 2. Auflage, Thieme 1982
- 2. W. D. Keidel (Hrsg.): Kurzgefaßtes Lehrbuch der Physiologie, 4. Auflage, Thieme 1975

Conversion of Unit

	kPa	Pa=N/m ²	bar	mbar	mmHg	atm	at	psi
kPa	1	1000	0.010	10	7.501	9.869E-03	1.020E-02	0.145
Pa = N/m²	1.000E-03	1	1.000E-05	1.000E-02	7.500E-03	9.870E-06	1.020E-05	1.450E-04
bar	100	1.000E+05	1	1000	750	0.987	1.020	14.504
mbar	0.100	100	1.000E-03	1	0.750	9.869E-04	1.020E-03	1.450E-02
mmHg	0.133	133.330	1.330E-03	1.333	1	1.316E-03	1.360E-03	1.934E-02
atm	101.325	1.013E+05	1.013	1013.250	760	1	1.033	14.696
at	98.068	9.807E+04	0.981	980.680	735.294	0.968	1	14.228
psi	6.895	6.895E+03	6.895E-02	68.948	51.715	6.805E-02	7.029E-02	1

To convert e. g. [Pa] to [bar] proceed as follows:

- 1. look for the unit [bar] in the 1.line (4. column in the 1.line),
- 2. step down the column until you find the conversion factor for the second unit [Pa] (3.line),
- 3. result is the equation: p [bar] = 1.000E-05 * p [Pa].

NOTE: $1 \ bar = 100 \ kPa = 14.5 \ psi$.

Temperature

$$T[^{\circ}F] = \frac{9}{5} \cdot \left(T[^{\circ}C] + 32\right)$$

$$T[^{\circ}C] = \frac{5}{9} \cdot (T[^{\circ}F] - 32)$$

Default Values

 $T = 37 \, ^{\circ}C \quad (98.6 \, ^{\circ}F)$

RQ = 0.84 $FIO_2 = 0.21$

 $tHb = 15 \text{ g/dL} \qquad (9.3087 \text{ mmol/l})$

adult / fetal = adult

 P_{50} adult = 26.7 mmHg (3.578 kPa) P_{50} fetal = 21.5 mmHg (2.881 kPa)

Calculated Values

The calculated values are as far as possible and meaningful accorded to the NCCLS standard.

Following calculated values are available in the AVL COMPACT 3:

Calculated values	term NCCLS	term COMPACT	NCCLS conform.	Remark
Bicarbonate	HCO ₃	HCO3	yes	NCCLS formula (8)
Total CO ₂ in plasma	ctCO ₂	TCO2	yes	NCCLS formula (7)
Base excess (blood)	BE	BE	yes	NCCLS formula (15)
Base excess (blood) with SO_2 correction	_	BE_{act}	no	not defined in NCCLS
Base excess, extracellular	$\mathrm{BE}_{\mathrm{ecf}}$	BE_{ecf}	yes	NCCLS formula (14)
Buffer base	_	BB	_	not defined in NCCLS
Standard pH value	_	st.pH	_	not defined in NCCLS
Standard Bicarbonate	HCO _{3st}	st.HCO3	no	defined in NCCLS section 5.10, without formula
Oxygen saturation	SO_2	O2sat	partly	NCCLS conforming, only with datalink to oximeter
Oxygen content	ctO ₂	O2cont	yes	in NCCLS not special defined, but is in accordance to the corresponding calculation steps for Shunt
Alveolar arterial oxygen partial pressure difference	PAO ₂ -PaO ₂	AaDO ₂	yes	NCCLS formulas (16) and (17)
Hydrogen ion concentration	_	сН+	_	not defined in NCCLS
Standardized ionized Calcium	_	nCa _{pH=7.4}	_	not defined in NCCLS
PO ₂ at patient temperature	PO_2^{t}	PO2T	yes	NCCLS formula (25)
PCO ₂ at patient temperature	PCO_2^{t}	PCO2T	yes	NCCLS formula (24)
pH at patient temperature	pH^t	pHt	yes	NCCLS formula (23)
relative Shunt volume	$\frac{\dot{Q}s}{\dot{Q}t}$	Shunt	partly	NCCLS formula (19) if $P_aO_2 > 150$ mmHg

Equations¹

Hydrogen Ion Concentration, cH⁺

Concentration (activity) of hydrogen ions

$$c_{\text{H}^{+}} = 10^{(9-\text{pH})}$$
 [nmol/L] (5)

Bicarbonate, HCO3

Bicarbonate concentration in plasma

$$cHCO_3^- = PCO_2 \cdot 10^{(pH-7,618)}$$
 [mmol/L] (6)

Total CO₂ in Plasma, ctCO₂

Total concentration of CO₂ in plasma, the sum of dissolved CO₂ and bicarbonate.

$$ctCO_2(P) = cHCO_3^- + (0.0307 \cdot PCO_2)$$
 [mmol/L] (7)

Base Excess in blood, BE

The base excess of the blood results from a calculation to determine the titratable base of the blood, which in principle is measured by titration of the blood with a strong acid or base to a pH of 7.4 with $PCO_2 = 40$ mmHg at 37 °C.

[mmol/L] (10)

$$BE_B = (1 - 0.014 \cdot ctHb) \cdot [(1,43 \cdot ctHb + 7,7) \cdot (pH - 7,4) - 24,8 + cHCO_3^-]$$

Base Excess extracellular,

BE_{ecf}

The base excess of extracellular fluid is a quantity that reflects only the non-respiratory components of acid-base balance (ctHb = 5 g/dL).

$$BE_{acf} = 16.2 \cdot (pH - 7.4) - 24.8 + cHCO_3^{-1}$$
 [mmol/L] (11)

¹ refer "Rechenwerte HM-HR", Rev. 8, 29.April 1997

Buffer base, BB

The buffer base is the concentration of buffering anions which is available in whole blood to buffer strong acids and consists mainly of protein anions and bicarbonate. Of the protein anions, hemoglobin is the most significant.

$$BB = BE_B + 41.7 + 0.42 \cdot ctHb$$
 [mmol/L] (12)

Oxygen Saturation, SO₂

The amount of oxyhemoglobin in blood expressed as a fraction of the amount of hemoglobin <u>able to bind</u> oxygen (oxyhemoglobin plus deoxyhemoglobin) is termed, hemoglobin oxygen saturation

$$SO_2 = \frac{cO_2Hb}{cO_2Hb + cHHb} \cdot 100$$
 [%] (13)

If not calculated or from a direct measurement available:

$$SO_2\% = \frac{Q}{Q+1} \cdot 100$$

Adult:

$$lgQ = 2.9 \cdot lgPO_2^k + F1 \cdot 10^{-F2 \cdot PO_2^k} - F3$$

$$\lg PO_2^k = \lg PO_2 + 0.48 \cdot (pH - 7.4) - \lg(\frac{P_{50}}{26.7}) + 0.0013 \cdot BE_B$$

 $P_{50} = 26,7$ or enter P_{50} adult

$$F1 = 1,661$$
 $F2 = 0,074$ $F3 = 4.172$

Fetal:

$$\lg Q = 2.9 \cdot \lg PO_2^k + F1 \cdot 10^{-F2 \cdot PO_2^k} - F3$$

$$\lg PO_2^k = \lg PO_2 + 0.48 \cdot (pH - 7.2) - \lg(\frac{P_{50}}{26,7}) + 0.0013 \cdot BE_B$$

 $P_{50} = 21.5$ or enter P_{50} fetal

$$F1 = 1,3632$$
 $F2 = 0,0533$ $F3 = 4,113$

In this table the fetal P50-value is for pH=7.4 and should be preferred to use.

Oxygen Content, ctO,

Oxygen content is the sum of oxygen bound to hemoglobin as O_2Hb and the amount of oxygen dissolved in the plasma. This value is calculated from the measured O_2Hb and ctHb if available and is estimated from the calculated SO_2 if the measured O_2Hb is not available and if the calculation of oxygen saturation is selected.

The oxygen content of the CO-Oximeter does not contain the physical dissolved part and has to be completed.

With COOX data (AVL 912: O2ct)

$$C_{102} = O_2 ct + 0.00314 PO_2$$
 [ml/dL] (15)

No COOX data

$$C_{\text{tO}_2} = 1.39 c_{\text{Hb}} SO_2 + 0.00314 PO_2$$
 [ml/dL] (15)

for SO₂ see above

$$SO_2 = f(PO_2, pH, P_{50}, a/f, BE)$$
 (13)

Standard pH, pH_{st}

Standard pH of the blood is defined as the pH value of a blood sample which has been equilibrated at 37 °C with a gas mixture having a $PCO_2 = 40$ mmHg.

[pH-unit] (17)

$$pH_{st} = (0.8262 - 0.01296 \cdot atHb + 0.006942 \cdot BE) \cdot lg(0.025 \cdot PCO_2) + pH$$

Standard Bicarbonate, cHCO_{3st}

Standard bicarbonate of the blood, defined as the plasma bicarbonate concentration in blood which has been equilibrated at 37 °C with a gas mixture having a $PCO_2 = 40$ mmHg.

$$cHCO_3^{-}_{st} = 10^{(pH_{st}-6.022)}$$
 [mmol/L] (18)

Relative Shunt volume

The value $\frac{\dot{Q}s}{\dot{Q}t}$ is the fraction of venous blood that remains unoxygenated

after traveling from the right side of the heart to the left side of the heart. This fraction includes the effects of true shunts (i.e., anatomic shunts and true capillary shunts) along with the effects of a ventilation-perfusion mismatch. The extent of shunting is assessed after having the patient breath pure oxygen for about 15 minutes until there is adequate washout. The resulting high PAO_2 value allows the assumption that the end-capillary blood contains an amount of oxygen equal to the oxygen carrying capacity of hemoglobin, plus the maximum amount of oxygen soluble in plasma.

$$\frac{\dot{Q}_{S}}{\dot{Q}_{t}} = \frac{c_{tO_{2}}c - c_{tO_{2}}a}{c_{tO_{2}}c - c_{tO_{2}}\overline{v}}$$
(25)

with

$$c_{tO_2} \mathbf{a} - c_{tO_2} \overline{\mathbf{v}} \approx 5,15 \quad \text{ml / dL}$$

 $c_{tO_2} \mathbf{c} \approx c_{tO_2} \mathbf{A}$

Calculation of c_{tO_2} A

$$c_{tO_2} A = 1.39 c_{tHb} S_a O_2 + 0.00314 P_a O_2$$
 ml/dL

for PaO_2 see equation (35).

Calculation of c_{tO_2} a:

see equation (13), p 12-22 and equation (15), p 12-23.

Calculation of $c_{\mathrm{tO_2}} \overline{\mathrm{v}}$:

With COOX data AVL 912: $c_{\text{tO}_2} \overline{\text{V}}$, $c_{\text{tHb}} a$, $c_{\text{tHb}} \overline{\text{V}}$)

$$c_{\rm tO_2} \mathbf{a} = \frac{c_{\rm tHb} \mathbf{a}}{c_{\rm tHb} \overline{\mathbf{v}}} c_{\rm tO_2} \overline{\mathbf{v}} + 0,00314 P_{\overline{\mathbf{v}}} O_2 \qquad \qquad \mathrm{ml/dL}$$

Without COOX data and with measured mixed venous PO_2 -value the equations (13) and (15) are used for the calculation of C_{tO_2} \overline{V} -value.

Without COOX data and without measured mixed venous PO_2 -value the equation (15) is used for the calculation of c_{tO_2} value

The above described relations are only available for a body-temperature of 37 °C. Is the patient temperature other than 37 °C the numerical results are senseless and therefore are not printed.

Standardized Ionized Calcium, $niCa_{pH=7.4}$

The ionized Calcium value is standardized to pH = 7.4.

$$niCa^{++} = Ca^{++} \cdot 10^{F5 \cdot (pH-7.4)}$$

$$F5 = \begin{cases} 0.22 & \text{for blood} \\ 0.24 & \text{serum/plasma} \end{cases}$$
 [mmol/L] (28)

In the AVL COMPACT 3 only the blood parameter will be calculated.

pH at Patient Temperature, pH^t

pH- value corrected to patient temperature other than 37 °C.

$$pH^{t} = pH - [0.0147 + 0.0065 \cdot (pH - 7.4)] \cdot (t - 37)$$
 [pH-unit] (30)

PCO₂ at Patient Temperature, PCO₂^t

PCO₂-value corrected to patient temperature other than 37 °C.

$$PCO_2^t = PCO_2 10^{0.019(t-37)}$$
 [mmHg] (32)

PO₂ at Patient Temperature, PO₂^t

PO₂-value corrected to patient temperature other than 37 °C.

$$PO_{2}^{t} = PO_{2} \cdot 10^{\left[\frac{5.49 \cdot 10^{-11} \cdot PO_{2}^{3.88} + 0.071}{9.72 \cdot 10^{-9} \cdot PO_{2}^{3.88} + 2.30}\right](t-37)}$$
 [mmHg] (33)

Alveolar Arterial Oxygen Tension Difference, AaDO2t

If measured values are reported after correction to patient temperature, these temperature corrected values should also be used for the further calculation of parameters dependent on these variables.

The alveolar to arterial oxygen tension gradient ($PAO_2 - PaO_2$) is the difference between the alveolar oxygen tension, estimated above, and the measured oxygen tension of arterial blood.

$$\begin{aligned} \text{AaDO}_{2}^{t} &= P_{\text{A}} \text{O}_{2}^{t} - P_{\text{a}} \text{O}_{2}^{t} \\ \text{with} \\ P_{\text{A}} \text{O}_{2}^{t} &= (\text{Baro} - P \text{H}_{2} \text{O}^{t}) \cdot F \text{IO}_{2} - P_{\text{A}} \text{CO}_{2}^{t} \cdot \left[F \text{IO}_{2} + \frac{1 - \text{FIO}_{2}}{\text{RQ}} \right] \\ \text{and} \\ P \text{H}_{2} \text{O}^{t} &= 47 \cdot 10^{(t - 37)(0.0237 - 0.0001(t - 37))} \\ P_{\text{A}} \text{CO}_{2}^{t} &= P_{\text{a}} \text{CO}_{2}^{t} \end{aligned}$$

Base Excess in blood, BE_{act}

The base excess of th blood in consideration of the actual oxygen saturation. This extended equation permits an exact determination of the BE from venous and mixed venous blood,

[mmol/L] (43)

$$BE_{(act)} = (1 - 0.0143 \cdot ctHb) \cdot \left[(1.63 \cdot ctHb + 9.5) \cdot (pH - 7.4) - 24.26 + cHCO_{3}^{-} \right] - 0.2 \cdot ctHb \cdot \left(1 - \frac{SO_{2}}{100} \right)$$

Units of Measuring and Input Values of the Following Equations

pH	pH-unit	P 50	mmHg
<i>P</i> CO ₂	mmHg	a/f	-
<i>P</i> O ₂	mmHg	RQ	-
<i>c</i> tHb	g/dL	<i>F</i> IO ₂	-

Conversion of Units

 $\label{eq:solution} \text{SO}_{2cont} \ \quad 1 \ vol\% \, = 0,4464 \ mmol/l$

 $tHb \ 1 \ g/dL = 10 \ g/l = 0.6206 \ mmol/l$

Baro....... 1 mmHg = 1.3333 mbar = 0.1333 kPa

Short Term

a: venous

A: alveolar t: patient temperature

Literature

- [1] NCCLS: Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard, NCCLS Document C12-A Vol. 14 No. 11, September 1994
- [2] Zander R.Correct determination of blood base excess (BE, mmol/l) in Blood; Anastesiol Intensived Notfallmed Schmerzther (Germany), Oct 1995, 30 Suppl 1 p41-42.
- [3] Marsoner HJ. Acid base and oxygenation algorithms. Mediquip 1 (1982): 1.

Care and Maintenance of Remembranable pH / Blood Gas Electrodes

This section describes the care and maintenance required for optimal electrode performance.

Electrode performance is one of the most important factors influencing the quality of analytical results. Proper care and maintenance is required at regular intervals.

ATTENTION! No electrodes should be removed during calibration or measurement. Please wait until the process has been completed.

Maintenance is only necessary when an alarm occurs. Before beginning with maintenance, the program function "System test" and "Electrodes" for example, must be activated. This program can only be terminated by pressing [ESC] and does not have a timeout function.

NOTE: Before performing electrode maintenance disconnect the electrode cable and remove the electrode clip. Handle the electrodes with care ensuring that electrode tips do not contact any hard surface.

In the following section the maintenance procedures for the different types of electrodes (pH, PCO₂, PO₂) are described.

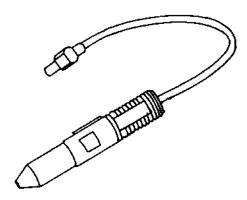


Fig. 12-1: Remembranable pH / Blood Gas Electrode

pH Electrode

The pH Electrode consists of the inner electrode and the housing and is marked with a gray grip. The pH Electrode requires only little maintenance.

To perform maintenance of the pH Electrode, do not interrupt a calibration or measurement.

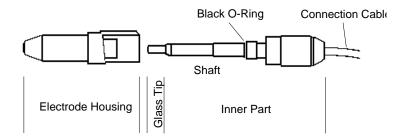


Fig. 12-2: pH Electrode

Replacement of the pH Electrode Housing

In case of a pH Electrode alarm or any other pH Electrode related problem remove the pH Electrode clip and take the electrode out of the measuring chamber block, by pulling it towards in rear.

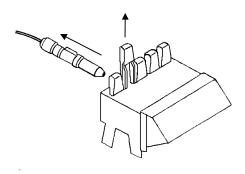


Fig. 12-3: Pull out the pH Electrode

Carefully remove the pH Electrode housing.

Dispose of the electrode housing according to applicable safety regulations or procedures.



Fig. 12-4: Remove pH Electrode housing

Replace the inner electrode O-ring if necessary (e.g. if brittle, or worn).

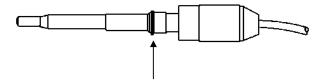


Fig. 12-5: Inner electrode - O-Ring

Fix new pH Electrode housing.

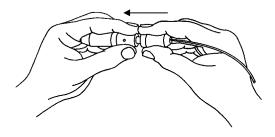


Fig. 12-6: pH Electrode: fix new housing (1)

NOTE: Press forefinger against the tip of the housing to avoid forcing out the Oring at the tip.

Without releasing the pressure, rotate the inner section one quarter turn in both directions.

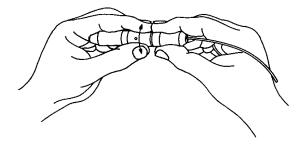


Fig. 12-7: pH Electrode: fix new housing (2)

NOTE: This procedure avoids, that the inner part is pushed back out of the housing after it is released (due to the elasticity of the O-ring).

Reinstall the pH Electrode in the measuring chamber block and reconnect the electrode cable and electrode clip.

Close the cover and initiate pH calibration.

NOTE: Should the pH Electrode (complete or inner element only) be exposed to air for more than two hours, place it in a small cup filled with Buffer Type 1. Immerse the top approx. 5 mm in this solution for 12 hours before reinstalling the electrode in the measuring chamber.

Place a soft cloth at the bottom of the glass cup in which the pH Electrode or its inner part is stored.

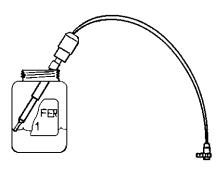


Fig. 12-8: pH Electrode: immerse into Buffer 1

Cleaning the pH Electrode

NOTE: This cleaning should be performed only in case of heavy soiling of the electrode tip. This procedure should be carried out no more than two or three times a year.

Carefully remove the pH Electrode as described before.

Remove and dispose of the electrode housing according to applicable safety regulations or procedures.

Replace the electrode O-ring if necessary (e.g. if brittle, or worn).

Moisten the chamois leather of the electrode cleaning box with a few drops of distilled water.

Squeeze a small amount of electrode cleaning paste onto the moistened chamois leather.



Fig. 12-9: pH Electrode: cleaning procedure (1)

Hold the electrode vertically between thumb and forefinger and polish it in circular movements with the chamois leather for about 15 seconds.

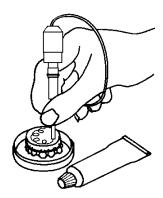


Fig. 12-10: pH Electrode: cleaning procedure (2)

Remove any remaining cleaning paste from the electrode with distilled water and a clean moistened tissue, applying slight pressure.

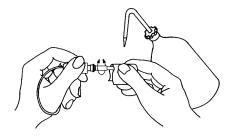


Fig. 12-11: pH Electrode: cleaning procedure (3)

Immerse the electrode tip in Buffer Type 1 for at least one hour (optimal 12 hours).

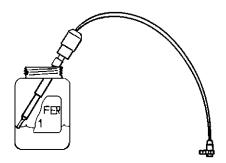


Fig. 12-12: pH Electrode: immerse into Buffer 1

Attach a new pH Electrode housing and reinstall the electrode in the measuring chamber block.

Reconnect the electrode connector and the electrode clip.

Close the cover.

Initiate a pH 2P calibration.

PCO₂ Electrode

The PCO₂ Electrode consists of the inner electrode, the housing with the membrane and the electrolyte solution and is marked with a green grip.

The membrane housing should be replaced periodically. Membrane replacement can be easily performed by the operator.

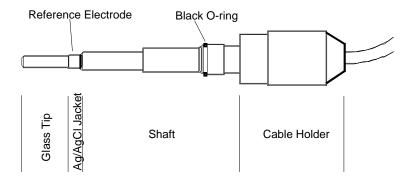


Fig. 12-13: PCO₂ Electrode

NOTE: Do not use abrasive cleaning solutions, which may damage the inner element.

Make sure that the electrolyte solution is free of air bubbles. The inner element and the entire electrode must never dry out.

The inner element or the entire electrode must be stored in PCO_2 Filling Solution with the Ag/AgCl electrode ring completely immersed.

NOTE: Never allow the tip of the glass electrode to touch hard surfaces (e.g. glass).

Place a soft cloth at the bottom of the glass cup in which the PCO₂ Electrode or its inner part is stored.

To replace the membrane housing, see page 12-41.

Cleaning before Replacing the Housing

The PCO₂ Electrode is marked with a green grip.

Disconnect the cable from the PCO_2 Electrode, pull out its clip and remove the electrode from the measuring chamber.

Carefully remove the inner element from the housing avoiding spillage of electrolyte solution.

Dispose of the old electrode housing according to applicable safety regulations or procedures.



Fig. 12-14: PCO₂ Electrode: remove Inner element

Replace the inner O-ring if necessary (e.g. if brittle, or worn).

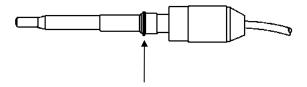


Fig. 12-15: PCO₂ Electrode: Inner element

Clean shaft of the inner part, glass tip and Ag/AgCl ring with a tissue moistened with distilled water.

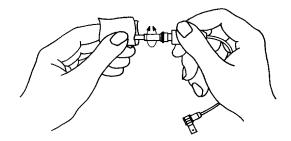


Fig. 12-16: PCO₂ Electrode.: cleaning shaft

Check whether the Ag/AgCl ring displays a uniform dark brown color. If the Ag/AgCl ring displays white spots, contact your service office.

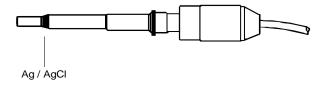


Fig. 12-17: PCO₂ Electrode: inner shaft

Rinse glass tip, Ag-AgCl-ring and shaft very carefully with distilled water. Dry the complete inner shaft with a clean tissue.

Cleaning of the Glass Tip

NOTE: Perform only 2 or 3 times a year, if the glass tip of the electrode is heavily soiled!

The PCO₂ inner electrode should be cleaned when it looks contaminated.

Carefully remove the PCO₂ Electrode from the measuring chamber.

Remove and dispose of the green electrode housing according to applicable safety regulations or procedures.

Replace the electrode O-ring if necessary (e.g. if brittle, or worn).

Moisten the chamois leather of the electrode cleaning box with a few drops of distilled water.

Squeeze a small amount of electrode cleaning paste onto the moistened chamois leather.



Fig. 12-18: PCO₂ Electrode: cleaning procedure (1)

NOTE: Do not attempt to clean the Ag/AgCl brown ring of the electrode with electrode cleaning paste.

Holding the electrode between your thumb and forefinger, polish it with the chamois leather for about 15 seconds with circular movements, applying slight pressure.

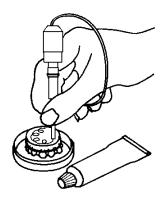


Fig. 12-19: PCO₂ Electrode: cleaning procedure (2)

Remove any cleaning paste from the electrode with distilled water and a clean moistened tissue.

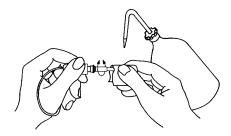


Fig. 12-20: PCO₂ Electrode: cleaning procedure (3)

Immerse electrode tip into PCO_2 Filling Solution for at least one hour (optimal 12 hours).

Fit a new PCO_2 Electrode housing (see page 12-41), fill the housing with PCO_2 Filling Solution and insert the inner part into the housing.

Reinstall PCO₂ Electrode into the measuring chamber block, secure the electrode clip and reconnect the electrode plug.

Close the cover.

Initiate the corresponding calibration.

PO₂ Electrode

The PO_2 Electrode consists of the inner electrode, the housing with the membrane and the electrolyte solution and is marked with a blue grip. The membrane housing should be replaced periodically. Membrane replacement can be easily performed by the operator.

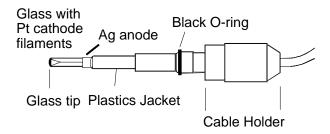


Fig. 12-21: PO2 Electrode

NOTE: Do not use abrasive cleaning solutions, which may damage the inner element

The inner element or the entire electrode should be stored in PO_2 electrolyte solution.

NOTE: Never allow the tip of the glass electrode to touch any hard surface (e.g. glass). Place a soft cloth at the bottom of the glass cup in which the PO₂ Electrode or its inner part is stored.

To replace the membrane housing, see page 12-41.

Cleaning

Carefully disconnect the PO_2 Electrode cable by pulling the plug gently. Release its clip and remove the electrode from the measuring chamber block.

Carefully remove the inner electrode from the housing avoiding spillage of electrolyte solution.

Dispose of the old electrode housing according to applicable safety regulations or procedures.

Replace the inner O-ring if necessary (e.g. if brittle, or worn).

Moisten the chamois leather of the electrode cleaning box with a few drops of distilled water.

Squeeze a small amount of electrode cleaning paste on to the moistened chamois leather.



Fig. 12-22: PO₂ Electrode: cleaning procedure (1)

Hold the electrode between your thumb and forefinger, polish it with the chamois leather for about 15 seconds in circular movement, applying slight pressure.

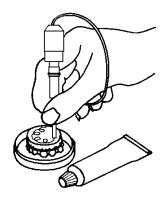


Fig. 12-23: PO₂ Electrode: cleaning procedure (2)

Remove any remaining cleaning paste from the electrode with distilled water and a clean moistened tissue.

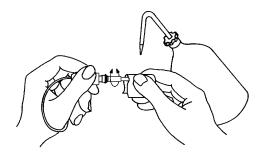


Fig. 12-24: PO₂ Electrode: cleaning procedure (3)

Dry the complete inner shaft with a clean tissue.

Attach a new PO₂ Electrode housing, filled with PO₂ Filling Solution.

Reinstall PO_2 Electrode into the measuring chamber block, fit the electrode clip and reconnect the electrode plug.

Close the cover.

Initiate the corresponding calibration.

Replacing the Membrane Housing of PCO₂ and PO₂ Electrodes

NOTE: Before replacing the electrode housing of the PCO₂ Electrode a special cleaning procedure is necessary (for details, please refer to page 12-34).

Take a new electrode housing for PCO_2 Electrode (green) or PO_2 Electrode (blue). Remove its white protective cap.

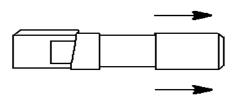


Fig. 12-25: Electrode housing with protective cap

Fill the electrode housing with PCO_2 or PO_2 Filling Solution by holding the housing in a slightly inclined position and inserting the tip of the PCO_2 or PO_2 Filling Solution bottle.

Fill the housing to the overflow opening.

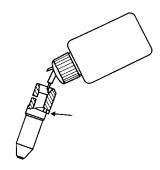


Fig. 12-26: Filling electrode housing with electrolyte

Gently tap the electrode housing to remove any air bubbles from the tip.

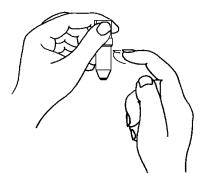


Fig. 12-27: Remove air bubbles

Incline the housing slightly with the overflow hole downwards. Carefully insert the inner electrode until resistance is felt.

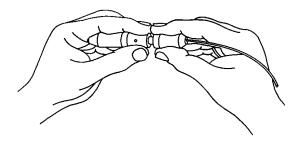


Fig. 12-28: Insert inner part

Insert the inner electrode until it is flush with the housing. Rotate the inner section one quarter in both directions.

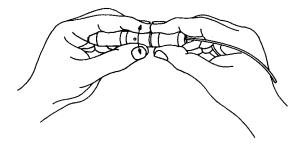


Fig. 12-29: Insert inner part

NOTE: Slightly turn the inner part of the electrode, for optimal membrane tension. This also prevents the inner element from being pushed back out of the housing after release, due to the elasticity of the O-ring.

Dry the electrode carefully with a tissue. Close the overflow hole of the housing with coroplast adhesive tape (10 mm x 10 mm).

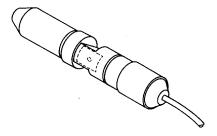


Fig. 12-30: Close overflow hole of the electrode housing

ATTENTION! Make sure that the tape does not overlap onto the two lateral flat spots of the electrode housing, as this could create difficulties inserting the electrode clip.

When the inner part is inserted into the electrode housing silicon grease is extruded.

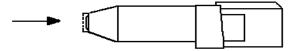


Fig. 12-31: Silicon grease of the tip of the electrodes

Remove this grease with a cotton swab or tissue. When using a tissue, double it to be able to remove the silicon grease in the space between O-ring and membrane with the tip of the tissue.

Reinstall PCO₂ Electrode or PO₂ Electrode into the measuring chamber block, fit the electrode tip and reconnect electrode plug.

Close the cover.

Initiate the corresponding calibration.

NOTE: If a warning or a alarm is displayed during calibration, try to recalibrate once again, then repeat replacement of the membrane.

Operating Principles

A detailed description of analytical principles and individual component functions is described in this chapter.

Principle of pH Measurement

When pH-sensitive glass is dipped into an aqueous solution, water molecules may diffuse into the structure of the glass and form a hydrated swell layer. This layer is able to absorb hydrogen ions (protons).

This creates an electrical potential, which depends on the degree of acidity or on the activity of the hydrogen ions respectively, and thus on the pH-value of the solution.

ACID: Substance that is able to release H^+ ions (proton-donor)

BASE: Substance that is able to accept H^+ ions (proton-acceptor).

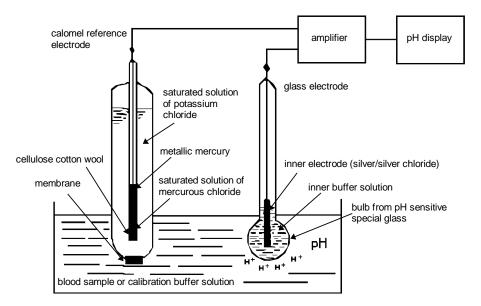


Fig. 12-32: Operating principles - pH Electrode

pH Electrode and pH-Reference Electrode

The pH Electrode consists of a single glass tube whose bottom part is covered with special glass. In the area between inner and outer swell layer, an electric potential is generated.

To determine the value of this electric potential, the circuit has to be closed. On the inside of the glass electrode, electrical contact is made by an Ag/AgCl Electrode, on the outside by the pH Reference Electrode.

The pH Electrode comprises the following parts:

- an electrode body which consists of a pH-glass electrode;
- an electrode housing.

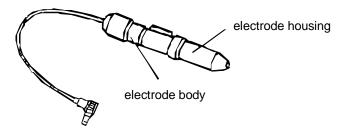


Fig. 12-33: pH Electrode

The pH Reference Electrode includes the following components:

- an inner part which contains mercury;
- an electrode housing which comprises a membrane and reference electrolyte.

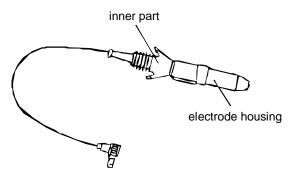


Fig. 12-34: pH Reference Electrode

Principle of CO₂ Partial Pressure (PCO₂) Measurement

The construction of the PCO_2 measuring system is shown in the Fig. 12-35. The direct PCO_2 measurement used in the AVL COMPACT 3 is a modification of the galvanic pH measurement.

A pH-glass electrode and an Ag/AgCl Reference Electrode form the outer part that is surrounded by a common electrolyte solution. They are separated from the blood sample or calibration gas by a CO₂ permeable but not ion-

permeable membrane. CO_2 diffuses in both directions through the membrane until an equilibrium is established between CO_2 partial pressure of sample and CO_2 partial pressure of the very thin electrolyte layer between membrane and glass electrode.

At this time the pH value of the electrolyte solution has been changed by chemical reaction. This pH change is measured, amplified and indicated as *PCO*₂-value.

$$CO_2 + H_2O \Leftrightarrow H_2CO_3 \Leftrightarrow H^+ + HCO_3^-$$

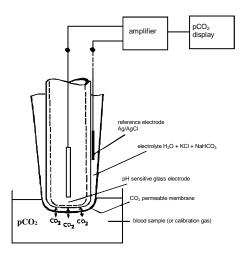


Fig. 12-35: Operating principles - PCO₂ Electrode

PCO₂ Electrode

The PCO₂ Electrode consists of:

- **Electrode body:** the electrode body is a pH-glass electrode provided with a silver-silver chloride coated anode.
- Electrode housing: the tip of the housing is covered by a CO₂ permeable membrane.
- **Membrane:** the two-foil membrane is sealed with silicon grease.
- Electrolyte: enables the chemical reaction and the transport of charges.

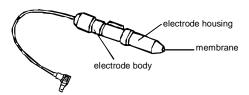


Fig. 12-36: PCO₂ Electrode

Principle of O₂ Partial Pressure (PO₂) Measurement

The PO₂ determination of the AVL COMPACT 3 is based on an electro-chemical process.

Oxygen molecules dissolved in an aqueous solution are reduced electro-chemically at a precious metal electrode (platinum cathode) with a constant potential of -0.7 V (polarization voltage) between the cathode and the pH- Reference electrode (anode). The electrons donated by the cathode and accepted by the anode produce an electric current within the solution. The outer part of the circuit is closed at the input circuit of the amplifier. Between cathode and membrane there is a very thin electrolyte layer. The O_2 diffusion through the membrane, dependent on the O_2 partial pressure (of the sample), continuously replaces the O_2 molecules of the electrolyte layer consumed during the cathode reaction. A very small constant current, representing the oxygen partial pressure PO_2 of the sample, passes through the electrode.

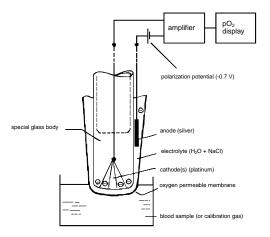


Fig. 12-37: Operating principles - PO₂ Electrode

PO₂ Electrode

The PO₂ Electrode consists of:

- **Electrode body**: the electrode body is a glass electrode, containing the cathode (4 platinum wires) and a silver anode.
- **Electrode housing:** the tip of the housing is covered by an O₂ permeable membrane.
- Membrane: the two-foil membrane is sealed with silicon grease.
- Electrolyte: enables the chemical reaction and the transport of charges.

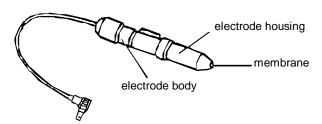


Fig. 12-38: PO₂ Electrode

Analytical Performance

Introduction

AVL verifies and checks continuously the specifications of the devices and measuring parameters by doing measurement series according to international directions, e.g. International Federation of Clinic Chemistry IFCC to guarantee the performance characteristics.

The following measuring data are an abstract of the results of the 510 k test series, all performed with AVL COMPACT devices.

Definitions

Standard

A substance to determine the concentration of the sample. All AVL calibration standard solutions and QC materials are prepared with known highly purified chemicals regarding e.g. NIST directions (National Institute of Standards and Technology).

Accuracy

Accuracy is the agreement between the mean estimate of a measurement series of a certain quantity and its true value.

Inaccuracy

Inaccuracy is the numerical difference X between the mean of a set of replicate measurements MV and the true value TV.

X = MV - TV

This difference may be expressed in the units in which the quantity is measured, or as a percentages of the true value.

Influences on the accuracy are:

- calibration cycle
- calibration solutions
- all not known systematic errors

Recovery

A simple verification of the accuracy can be done by determining the recovery. Recovery experiments include the measurement of two samples which are identical except that a known amount of pure chemicals are added to the sample. The following should be taken into account:

- the added chemicals must be completely dissolved
- the pure substance can have another matrix as having in their natural environment which can lead to interferences.

Imprecision

The imprecision is defined as the standard deviation SD of the results in a set of replicate measurements.

Repeatability (within Run)

Replicate measurements of identical sample during a short time period (e.g. minutes or hours) done by one person using one device.

Repeatability (between-Day or Day-to-Day)

Replicate measurements of identical samples during a longer time period (e.g. days) done by one person using one device.

Repeatability (between-Laboratories or between Instrument)

Replicate measurements of identical samples during a longer time period (e.g. days, weeks) done by some persons using different devices.

The following should be taken into account:

- kind of preanalytical preparations and handling of reagents and devices
- stability of the samples and the QC materials
- carry-over, drift ...

Comparison

The purpose of a correlation study is to evaluate the typical performance of the instrument in comparison to a legally marketed predicate device in order to demonstrate equivalence to existing methodology.

Requirements and Limitations

The stated situations must be granted by the operator:

- Correct set-up and installation on site of the AVL COMPACT 3 (see chapter 3).
- Use device only under correct environmental operating conditions.
- Use only AVL reagents with valid expiration date.
- Correct handling of reagents and samples, please refer to the package insert sheet and chapter 3.
- In same cases tonometered samples must be used. For accuracy and imprecision of this device the samples and procedures please refer to the recommendations of the tonometer manufacturer. The operator must be trained for using this devices and methods.
- pH-measuring values are obtained using AVL QC calibration materials.
- AVL recommends to use only reagents, gases and calibration materials with the same lot number to avoid additional uncertainties.

Measuring Conditions

Ambient temperature	. approx. 25 °C
Ambient air pressure	. 740 mmHg
Relative humidity	. approx. 50 %
Calibration cycles	default settings
Settings of conversion factors	. Slope: 1.000 (Intercept: 0.000)
Measuring temperature	. 37 °C
Whole blood tonometered at	. 37 °C

Verification of Performance Data

nnumber of samples

SDstandard deviation within a set of measurements

SD(Instr.).....standard deviation between instruments

TotSDtotal standard deviation

 \overline{X}mean value of a set of measurements

R.....recovery in %

Accuracy and Repeatability: pH-Parameter

The results of the measured data are compiled in the table below. (Specimen: aqueous and serum based QC material):

AVL CONFITEST

	\overline{X}	SD	TotSD	n
Level 1	7.207	0.002	0.004	40
Level 2	7.410	0.002	0.005	40
Level 3	7.630	0.002	0.005	40
Level 4	7.406	0.002	0.007	40

RNA Medical EQUILTM

	$\overline{\mathcal{X}}$	SD	TotSD	n
Level 1	7.178	0.002	0.009	40
Level 2	7.422	0.002	0.005	40
Level 3	7.732	0.002	0.005	40

RNA Medical QUALIDATATM

	Expected	$\overline{\mathcal{X}}$	SD	SD (Instr.)	R	n
Level 1	6.841	6.841	0.002	0.003	100.0	60
Level 2	7.099	7.100	0.002	0.003	100.0	60
Level 3	7.382	7.383	0.002	0.003	100.0	60
Level 4	7.598	7.600	0.002	0.003	100.0	60

Accuracy and Repeatability of PCO₂ Parameters

The results of the measured data are compiled in the following table:

Accuracy in Whole Blood

Expected	$\overline{\mathcal{X}}$	SD	R	n
[mmHg]	[mmHg]	[mmHg]	[%]	
10.2	10.4	0.24	98	20
28.9	28.7	0.32	101	20
35.5	35.4	0.46	100	20
41.8	41.3	0.36	101	20
54.9	55.2	0.63	99	20
67.7	69.0	0.38	98	20
75.5	76.0	0.71	99	20
82.1	82.7	1.20	99	20
94.1	96.6	1.08	97	20
119.1	124.2	1.24	96	20

AVL CONFITEST

	\overline{X}	SD	TotSD	n
	[mmHg]	[mmHg]	[mmHg]	
Level 1	18.780	0.2	0.3	40
Level 2	37.370	0.2	0.4	40
Level 3	63.360	0.2	0.5	40
Level 4	44.160	0.2	0.4	40

RNA Medical EQUIL $^{\mathrm{TM}}$

	$\overline{\mathcal{X}}$	SD	TotSD	n
	[mmHg]	[mmHg]	[mmHg]	
Level 1	74.220	0.6	1.1	40
Level 2	34.550	0.3	0.4	40
Level 3	11.020	0.1	0.2	40

RNA Medical QUALIDATA $^{\mathrm{TM}}$

	$\overline{\mathcal{X}}$	SD	TotSD	n
	[mmHg]	[mmHg]	[mmHg]	
Level 1	70.320	0.5	0.9	40
Level 2	44.490	0.2	0.2	40
Level 3	23.000	0.2	0.4	40

Accuracy and Repeatability of PO₂ Parameters

Accuracy in Whole Blood

		in the second se	i e	
Expected	$\overline{\mathcal{X}}$	SD	R	n
[mmHg]	[mmHg]	[mmHg]	[%]	
20.1	20.1	0.43	100	20
42.0	41.4	1.45	101	20
58.4	55.2	0.83	106	20
96.7	96.1	0.61	101	20
116.2	110.4	1.88	105	20
127.9	126.1	2.79	101	20
141.9	138.0	1.41	103	20
145.3	144.4	1.53	101	20
204.2	206.7	2.08	99	20
309.8	310.5	6.20	100	20

AVL CONFITEST

	$\overline{\mathcal{X}}$	SD	TotSD	n
	[mmHg]	[mmHg]	[mmHg]	
Level 1	148.710	0.9	1.7	40
Level 2	110.860	0.9	1.4	40
Level 3	74.120	0.8	1.4	40

RNA Medical EQUILTM

	$\overline{\mathcal{X}}$	SD	TotSD	n
	[mmHg]	[mmHg]	[mmHg]	
Level 1	149.140	1.2	2.0	40
Level 2	56.480	0.8	1.3	40
Level 3	20.540	0.7	0.7	40

RNA Medical QUALIDATA $^{\mathrm{TM}}$

	$\overline{\mathcal{X}}$	SD	TotSD	n
	[mmHg]	[mmHg]	[mmHg]	
Level 1	72.310	0.7	1.1	40
Level 2	110.750	0.9	1.5	40
Level 3	150.310	0.9	1.6	40

Comparison of PCO2 Measurement between Sample Types

Specimen: tonometered Whole Blood at 37 °C.

	PCO ₂ / mmHg				PCO ₂ / mmHg			
	Expected	$\overline{\mathcal{X}}$	SD	Recovery	Expected	$\overline{\mathcal{X}}$	SD	Recovery
	[mmHg]	[mmHg]	[mmHg]	[%]	[mmHg]	[mmHg]	[mmHg]	[%]
Syringe	17.8	18.1	0.23	101.6	41.2	42.1	0.35	102.1
Capillary	17.8	18.0	0.27	101.0	41.2	41.8	0.58	101.3
Mini Sample	17.8	17.8	0.45	99.8	41.2	41.6	0.88	100.8
Micro Sample	17.8	17.9	0.27	100.6	41.2	41.8	0.43	101.3
Total	17.8	18.0	0.32	100.8	41.2	41.8	0.59	101.4
Syringe	20.6	20.9	0.34	101.2	67.8	67.6	1.55	99.7
Capillary	20.6	20.9	0.26	101.2	67.8	68.6	0.55	101.2
Mini Sample	20.6	20.9	0.28	101.2	67.8	68.8	0.58	101.5
Micro Sample	20.6	20.6	0.35	100.1	67.8	69.7	0.57	102.8
Total	20.6	20.8	0.31	100.9	67.8	68.7	0.92	101.3
Syringe	27.5	28.1	0.37	102.3	68.8	70.5	0.60	102.5
Capillary	27.5	28.2	0.23	102.5	68.8	70.4	0.42	102.3
Mini Sample	27.5	27.6	0.26	100.6	68.8	69.7	1.05	101.4
Micro Sample	27.5	27.7	0.25	100.9	68.8	70.7	0.73	102.7
Total	27.5	27.91	0.28	101.6	68.8	70.3	0.73	102.2
Syringe	27.5	27.9	0.38	101.5	103.1	102.9	0.76	99.9
Capillary	27.5	28.0	0.55	101.7	103.1	103.5	0.90	100.4
Mini Sample	27.5	27.7	0.46	100.5	103.1	104.0	1.54	100.9
Micro Sample	27.5	27.7	0.42	100.5	103.1	104.0	1.68	100.9
Total	27.5	27.8	0.46	101.0	103.1	103.6	1.28	100.5
Syringe	37.7	38.2	1.07	101.3	139.5	139.5	1.64	100.0
Capillary	37.7	38.0	0.78	100.9	139.5	140.0	1.99	100.0
Mini Sample	37.7	38.7	0.35	102.8	139.5	137.6	2.80	98.7
Micro Sample Total	37.7 37.7	38.3 38.3	0.18 0.69	101.6 101.6	139.5 139.5	140.8 139.5	4.17 2.82	101.0 100.0
= 5 5 44 2	1				1	1	1	1

Comparison of PO2 Measurement between Sample Types

Specimen: tonometered Whole Blood at 37 °C.

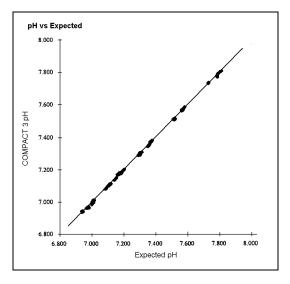
	PO ₂ / mmHg				PO ₂ / mmHg			
	Expected	\bar{x}	SD	Recovery	Expected	$\overline{\mathcal{X}}$	SD	Recovery
	[mmHg]	[mmHg]	[mmHg]	[%]	[mmHg]	[mmHg]	[mmHg]	[%]
Syringe	0	1.1	0.47		135.6	137.3	3.25	101.2
Capillary	0	0.9	0.47		135.6	136.3	1.24	100.5
Mini Sample	0	0.8	0.36		135.6	137.3	1.38	101.3
Micro Sample	0	0.7	0.57		135.6	137.8	1.14	101.6
Total	0	0.9	0.47		135.6	137.2	1.95	101.2
Syringe	21.0	20.9	0.53	99.6	300.7	290.8	3.60	96.7
Capillary	21.0	21.1	1.50	100.6	300.7	295.1	1.87	98.1
Mini Sample	21.0	20.7	0.60	98.7	300.7	294.1	8.18	97.8
Micro Sample	21.0	20.6	1.05	98.4	300.7	293.7	3.06	97.7
Total	21.0	20.8	1.00	99.3	300.7	293.4	4.81	97.6
Syringe	44.7	44.4	1.00	99.3	344.0	336.9	6.65	97.9
Capillary	44.7	44.4	1.12	99.3	344.0	342.1	4.07	99.5
Mini Sample	44.7	43.3	0.64	96.9	344.0	343.6	3.48	99.9
Micro Sample	44.7	43.3	0.88	96.9	344.0	343.6	9.93	99.9
Total	44.7	43.8	0.93	98.1	344.0	341.5	6.55	99.3
Syringe	76.0	77.1	0.61	101.4	501.2	492.1	11.11	98.2
Capillary	76.0	77.4	0.65	101.8	501.2	489.1	7.19	97.6
Mini Sample	76.0	78.3	0.51	103.0	501.2	486.7	8.36	97.1
Micro Sample	76.0	77.4	1.01	101.8	501.2	494.3	9.30	98.6
Total	76.0	77.5	0.72	102.0	501.2	490.5	9.11	97.9
Syringe	96.2	95.7	0.70	99.5	659.5	640.1	12.61	97.0
Capillary	96.2	96.7	0.96	100.5	659.5	647.7	11.80	98.2
Mini Sample	96.2	97.5	0.88	101.4	659.5	644.6	12.22	97.3
Micro Sample	96.2	97.1	1.10	101.0	659.5	641.6	20.55	97.3
Total	96.2	96.7	0.92	100.6	659.5	643.5	14.75	97.6

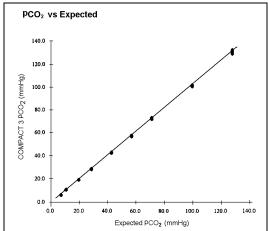
Comparison of pH Measurement between Sample Types

Specimen: tonometered Whole Blood at 37 °C.

	pH value			pH value	pH value			
	OMNI	$\overline{\mathcal{X}}$	SD	OMNI	$\overline{\mathcal{X}}$	SD		
<u> </u>	pH	6.074	0.007	pH	7.400	0.000		
Syringe	7.005	6.974	0.007	7.443	7.428	0.009		
Capillary	7.002	6.976	0.005	7.434	7.430	0.009		
Mini Sample	7.003	6.984	0.014	7.436	7.431	0.015		
Micro Sample	7.003	6.988	0.009	7.436	7.431	0.007		
Total	7.003	6.980	0.009	7.437	7.430	0.010		
Syringe	7.091	7.070	0.005	7.485	7.480	0.009		
Capillary	7.087	7.071	0.006	7.480	7.477	0.010		
Mini Sample	7.088	7.088	0.010	7.479	7.478	0.009		
Micro Sample	7.087	7.088	0.012	7.479	7.480	0.005		
Total	7.088	7.080	0.009	7.481	7.478	0.008		
Syringe	7.204	7.190	0.009					
Capillary	7.202	7.191	0.009					
Mini Sample	7.206	7.198	0.004					
Micro Sample	7.203	7.197	0.008					
Total	7.204	7.194	0.008					
Syringe	7.308	7.285	0.013					
Capillary	7.303	7.285	0.014					
Mini Sample	7.301	7.290	0.012					
Micro Sample	7.301	7.284	0.015					
Total	7.303	7.286	0.013					
Syringe	7.327	7.302	0.008					
Capillary	7.329	7.304	0.007					
Mini Sample	7.327	7.307	0.011					
Micro Sample	7.325	7.309	0.006					
Total	7.327	7.305	0.008					

Linearity of pH, PCO₂ and PO₂ in Tonometered Whole Blood





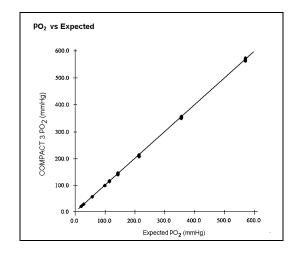
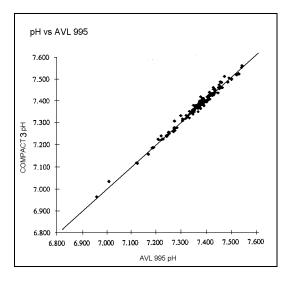
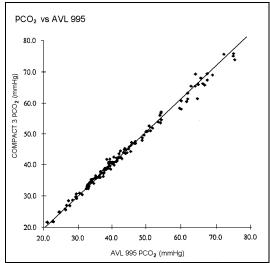


Fig. 12-39: Linearity of pH, PCO_2 and PO_2 in tonometered whole blood

Comparison Study with AVL 995





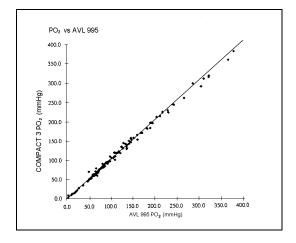


Fig. 12-40: Comparison study with AVL 995

Options

Barcode Scanner

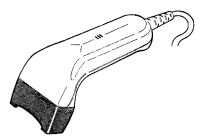


Fig. 12-41: Barcode scanner

A bar code scanner which scans in the patient number during measurement, can be installed optionally in the AVL COMPACT 3. In addition, the operators identification (Op. ID.) can be scanned in with the barcode scanner however, only in the READY condition.

When the barcode scanner is installed, the password and locking of the analyzer can be activated.

The reading units are pre-programmed for the code types

- 2by5 Interleaved
- Codabar
- Code 128
- Code 39.

For details, please refer to chapter 8 "Settings" and chapter 11 "Interfaces".

External Waste Container

In addition to the regular or reusable waste container, an external waste container with a fill volume of 4 litres (entire volume: 5 litres) is available.



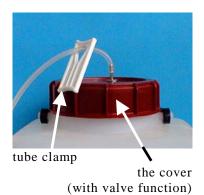




Fig. 12-42: External waste container

Installing the external waste container

(b)

- Connect the tube to the nipple of the adapter of the waste collector.
- Remove the cap from the waste collector.
- Open the bottle compartment cover.
- Screw the waste container cap onto the waste collector.
- Insert the bottle into its socket in the bottle compartment.
- When placing the tube to exit the bottle compartment (bottom right, see arrow Fig. 12.42a), make sure it will not be pinched when the bottle compartment cover is closed.
- Feed the tube through the tube clamp.

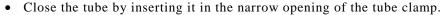
Attention: Do not pinch the tube!

- Remove the cap from the external waste container.
- Connect the other end of the tube to the nipple of the cover (with valve function, Fig. 12.42b) of the external waste container and screw the cover tight.

NOTE: Place the external waste container on the ground!

Discarding external waste container

At a fill level of 80 % (~ 4 l) of the total volume, the external waste container must be discarded.





- Remove the cover; close the external waste container with a sealing cap and discard in accordance with local regulations for biohazardous waste.
- Screw the cover onto a new external waste container.
- Open the tube clamp.

Discarding a waste container with a fill level exceeding 80 %



NOTE: The external waste container should not be filled above the marking. Discard the external waste container together with the cap in accordance with local regulations for biohazardous waste.

Decontamination / Cleaning

Decontaminate / clean the external waste container using a disinfectant in accordance with local regulations.

NOTE: Substances for odour control should be added only to the external waste container.

Troubleshooting

Check Waste

(see Chapter 10 – "Troubleshooting", Section – "Error Messages and Instructions for Elimination")

An external waste container with a fluid level exceeding 80 % has also filled the regular waste container.

The warning "Check Waste" is displayed.

Elimination: see "Discarding a waste container with a fill level exceeding 80 %"

Meas. path filled! / Check meas. path!

(see Chapter 10 – "Troubleshooting", Section – "Error Messages and Instructions for Elimination")

Check K0

(see Chapter 10 – "Troubleshooting", Section – "Printed Warnings and Error Messages")

The back pressure valve in the cover possibly leaks!

- Close the tube by inserting it in the narrow opening of the tube clamp.
- If this eliminate the error, replace the cover.
- If this does not eliminate the error, please call AVL customer support!

User Programs

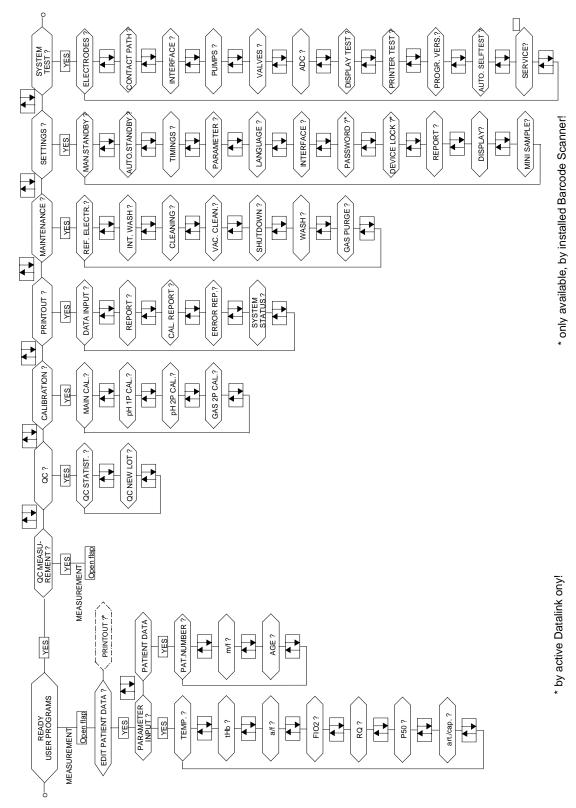


Fig. 12-43: User programs - AVL COMPACT 3

Fluidics

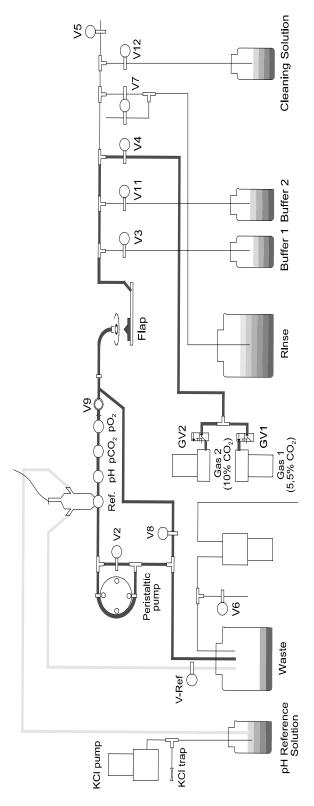


Fig. 12-44: Fluidics

13 PREANALYTICAL REQUIREMENTS FOR BLOOD GAS ANALYSIS

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13 Preanalytical Requirements for Blood Gas Analysis

Introduction

Blood gas and pH analysis is performed to obtain accurate measurement parameters indicating oxygenation and acid-base status of the patient. Known parameters are: PO_2 (partial oxygen pressure), PCO_2 (partial pressure of dissolved CO_2) and the pH value as a measure of acidity or alkalinity. The measurement values depend on sampling procedures, sampling containers, transport and storage as well as on the measurement itself.

Sample Types

Arterial Blood

In most cases, arterial blood obtained through arterial puncture is used for blood gas analysis. Regulations in various countries require the exclusive use of arterial blood for blood gas analysis. The advantage of this type of sample lies in the homogeneity of the arterial blood from a orta to peripheral circulation. Samples taken at the radial, brachial and femoral arteries yield identical results independent of the puncture site.

Venous Blood

For examining oxygenation, venous blood is suitable only as an additional component, i.e. for determining the difference of the oxygen content between arterial and venous blood.

Arterialized Capillary Blood

With an appropriate tissue puncture site, with proper preparation and taking into consideration contraindications, the values for pH and PCO_2 are not significantly different from those obtained with arterial blood. The values for the PO_2 , however, may be lower by up to 10% depending on the puncture site.

Sampling Procedures

Sampling Devices

- Syringe
- Capillary
- AVL Microsampler

Syringe

For arterial blood samples, glass syringes with easily movable glass or metal plungers are traditionally used. These guarantee that the gas exchange with ambient air and the resulting change in blood gas values remains negligible. Recently, syringes made from polymeric materials have also been used. Before using these syringes, their suitability for blood gas analysis will have to be established and/or guaranteed by the manufacturer, since certain plastic materials show significant permeability and solubility regarding oxygen and CO_2 . A change of the PO_2 and PCO_2 values in the sampling container caused by diffusion through the syringe walls would be the result.

Capillary

Capillary blood sampling is usually performed using glass capillaries. The capillary effect causes the sample to automatically flow from the puncture site into the capillary. Use only capillaries with thin even layers of heparin on the inside.

We recommend AVL glass capillaries (250 pcs./package, heparinized) Recently, capillaries made from polymeric materials are also being used. These are acceptable if testing has established that the solubility and permeability of the material with regard to gases (see plastic syringes) is sufficiently low.

AVL Microsampler

To facilitate arterial blood sampling, AVL developed the Microsampler kit. It allows sampling at the radial, brachial and femoral arteries in a very simple way causing only minor trauma to the punctured blood vessel.



Fig. 13-1: AVL Microsampler

The AVL Microsampler consists of a very thin needle (26 gauge, approx. 0.45 mm) at the tip of the kit, which is connected to two glass capillaries inside a holder.

The inside of each capillary is coated with an even layer of lyophilized (highly soluble) heparin to prevent coagulation of the sample in the sampling container. During normal puncture, the needle is completely inserted into the vessel; with the AVL Microsampler, only the tip penetrates the vessel. Immediately after penetration, the user can see the pulsating flow of blood into the capillary and thus verify that the tip of the needle is inside an arterial vessel (if the blood flow into the capillary is not pulsating, a vein was punctured).

The thin needle causes only minor trauma at the puncture site; the puncture lesion closes very quickly after the needle is retracted. Furthermore, the inner lumen of the needle reduces the arterial pressure, thus creating a slow blood flow into the capillary that can be observed by the user.

Anticoagulation

In the analysis of whole blood, coagulation during sampling must be prevented. We recommend the use of special syringes, which contain 0.05mL (concentration of approx. 1000 IU/mL) of lyophilized heparin. After sampling, the syringe is shaken carefully to mix the heparin contained in the dead space of the syringe and the sample thoroughly (contains glass or steel globule for this purpose).

AVL blood gas glass capillaries for sampling of capillary blood have an even heparin coating on the inside. When the sample is aspirated, the heparin is automatically absorbed by the sample and causes the desired anticoagulation effect.

Caution: Should the same sample be used for the measurement of blood gas and electrolyte values or other parameters, carefully select the heparin used in the syringe and capillary tube. For blood gas analysis, sodium heparin is used; for the determination of electrolytes, this type of heparin is undesirable. In this case, a mixture of sodium-lithium or sodium ammonium heparin (AVL No. MG0023) should be used.

The capillaries in the AVL Microsampler are likewise evenly coated with the required amount of lyophilized heparin and suitable for simultaneous blood gas and electrolyte testing.

Effect of Heparin on Measurement Parameters

In AVL glass capillaries, the selection of heparin substances and their concentrations is such that changes to the measurement values can be excluded. When other heparin salts are used, slight deviations in the values are possible.

Use of EDTA

Significant changes to measurement values may occur when EDTA or citrates are used.

Sampling Procedure

Preparation of Puncture Site

The puncture site is being cleaned and disinfected with alcohol (e.g. isopropyl alcohol, ethanol, etc.) in the usual manner.

Syringe Sampling

The ideal artery for puncture should be easily accessible, have a sufficient lumen, be at the surface and at a sufficient distance from veins or nerves. Supply by collateral vessels should also be sufficient so that, in case of an emergency, a sufficient supply remains. Above all, it should be easily accessible during puncture.

Selection of the artery will be governed by the expertise of the operator and patient comfort. In the past, the femoral artery was the preferred puncture site, but over the years, the brachial artery (caution: insufficient collateral supply!) and especially the radial artery were also being used.

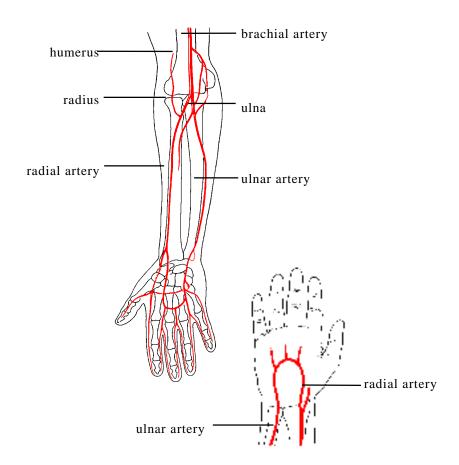


Fig. 13-2: Main arteries in the arm

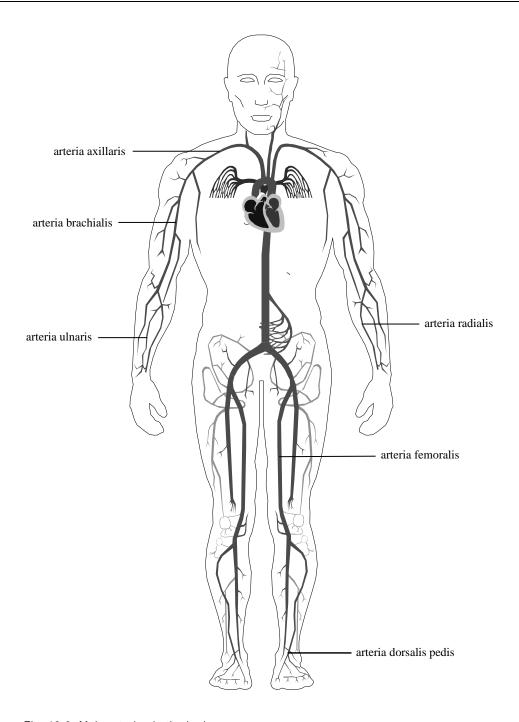


Fig. 13-3: Main arteries in the body

Traditional arterial puncture is performed using a syringe. In most cases, arterial pressure is sufficient to push back the syringe plunger automatically. If necessary, light retraction may support this procedure. Active suctioning, as is performed with venous blood sampling, should be avoided, if possible.

After removal of the needle, compression of the puncture site is required to prevent hematoma.

Microsampler Sampling

This type of blood sampling can also be performed at all sites described for syringe sampling using the AVL Microsampler. Sampling is particularly easy at the radial artery (see Fig. 13-2 and Fig. 13-3). The artery is located by palpation with index and middle finger. The two fingers are being applied to the left and the right of the artery in parallel to its flow direction. The fine needle is inserted into the vessel almost vertically between the two palpating fingers, with a slight incline to proximal. The needle is not fully inserted into the blood vessel, as is the case with syringe sampling, but only penetrates the surface. Successful penetration is indicated by a lightly pulsating blood flow into the capillaries, which also indicates that an artery was punctured, not a vein, and that the incision did not go completely through the artery. If that is the case, pull the needle back lightly, until blood starts flowing into the capillaries. When both capillaries are filled, quickly pull the needle out of the tissue and briefly compress the puncture site. The minute incision closes quickly and leaves no lesions or hematoma.



Fig. 13-4: Use of AVL Microsampler

Capillary Sampling

When circumstances do not allow arterial sampling or if repeated arterial puncture is not desirable or dangerous, arterialized capillary blood sampling may be selected as an alternative method. When properly performed, this type of sampling can be a substitute for arterial sampling and gives a true picture of the acid-base status. When sampling is performed on a hyperemized earlobe, the PO_2 value is also reliable.

The validity of capillary sampling depends mainly on two factors:

- Good vasodilatation through hyperemization of the puncture site.
- Elimination of all contamination risks by ambient air (can be difficult in some cases).

Use of capillary blood samples is contraindicated in the following cases:

- Patient in shock with centralized circulation. In this case, arterialized blood cannot be drawn from the capillary bed due to the opening of the subcutaneous capillary shunts.
- Increased central vein pressure, which causes an increase of venous blood in the capillary blood.
- Peripheral and local circulation problems which affect the puncture site.
- Cases in which the PO₂ values have to be very exact, for shunt determination, or in case of precise determination of high PO₂ values.

Performing capillary sampling

For capillary sampling, a careful selection of the puncture site is very important. Suitable sites are the earlobe (Fig. 14-6), the digital pulp and in case of newborn sampling, the heel (Fig. 14-5).



Fig. 13-5: Puncture of the heel (newborn)

Uninterrupted capillary circulation at the puncture site must be ensured to achieve results that correspond to those obtained with arterial blood sampling. The puncture site for capillary sampling should be hyperemized. For capillary sampling at the earlobe (adults), hyperemia will be created by medication. Hyperemia becomes apparent through skin discoloration (red) and the occurrence of itching or stinging. On the digital pulp, hyperemia is created through mechanical pressure or heat application. In newborns, the puncture site at the heel is usually not hyperemized.

The puncture itself is performed using sterile disposable lancets. The puncture should be deep enough, but no deeper than 3 mm. The first drop should be wiped off. With proper hyperemia, a second drop will appear immediately. The end of the capillary is held close to the incision and the blood will flow into the capillary until it is filled. The opening of the capillary should be covered by blood to prevent gas exchange.

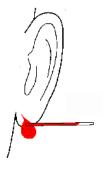


Fig. 13-6: Capillary puncture at the earlobe

Do not squeeze blood out of the puncture site. This will add tissue fluids, which cause a thin blood film, that quickly mixes with ambient air.

This will result in a falsification of the blood gas values.

Air-bubbles must be avoided, since they may cause contamination of the sample.

Sampling from a Catheter

This type of sampling is used, when therapeutic reasons require the installation of an arterial catheter.

With the aid of the catheter, repeated sampling can easily be performed. Usually the catheter is perfused with physiological saline solution containing heparin to prevent coagulation, to keep the catheter open. A three-way stop-cock is placed at the proximal end of the catheter for blood sampling purposes.

Two precautions have to be taken to ensure valid sampling:

- The catheter is to be flushed with a volume corresponding to four times its dead space before drawing a sample. To do this, the sampling syringe, which most commonly is connected to the three-way valve with a Luer-Lok connector, is slowly filled several times and emptied out into the catheter.
- Sample aspiration should be very slow and without evacuation, or should be automatic due to the arterial pressure.

Caution: Various medications may cause contamination of the measuring chamber of the blood gas analyzer. To avoid this, cleaning cycles should be performed at regular intervals.

Overview

Sample type	Sampling site	Sampling device (heparin.)	Sampling preparation (hygienic conditions are pre-requisite)	Sampling technique	Procedure
Arterial blood	Artery: - brachial - radial - ulnar - femoral - dorsalis pedis	Syringe	Check puncture site for uninter-rupted circulation	Macro puncture	Needle is completely inserted in blood vessel
		AVL Microsampler	Check puncture site for uninter-rupted circulation	Micro puncture	Only surface penetration of blood vessel
		Catheter	Rinse dead-space volume		
Capillary blood	- digital pulp - ear lobe (adult) - heel	Capillary	Hyper- emization	Capillary puncture	Pierce puncture site with lancet, then draw sample

Treatment of Sample Before Analysis

Transport and Storage

Both, blood gas analysis and acid-base analysis are acute analyses, i.e. the sample should be analyzed as soon as possible after sampling. Furthermore, it must be considered that due to heparinization, sedimentation of the sample is much faster than the blood sedimentation rate. If immediate analysis is not possible, the following measures have to performed:

- Immediately after sampling using a syringe, the air must be pushed out and the syringe must be sealed.
- If storage of the sample cannot be avoided, it should not exceed one hour, since the results will be clinically invalid thereafter. For this purpose, the sample must be cooled in ice. In some laboratories, cups filled with ice are being used. Immediately after the sample has been drawn, it must be completely submerged in ice. The sample container should be completely covered with ice. With modern blood gas analyzers, it is not necessary to warm up the sample before analysis. With older models, this may be necessary; roll the sample container in your hands for a few minutes.
- Samples in glass capillaries can be stored for at least one hour at room temperature without significant value changes.

Treatment of Syringe Samples Before Analysis

The following steps must be performed before analysis:

- Before analysis, the operator must ensure that no blood cell sedimentation occurred in the syringe. For this purpose, the operator must roll the syringe in his/her hands for thorough mixing of the sample.
- Before each analysis, the dead space volume of the syringe is discharged onto a gauze pad.
- Then the sample is injected into the device.

Summary

Following above procedures will minimize preanalytical influences on the sample. This ensures that the measurement values of the blood gas analyzer correspond to clinically relevant patient values.

In conclusion, a summary of the most important preanalytical factors in blood gas analysis:

Preparation of Puncture Site

- Check puncture site for collateral circulation
- Hygienic procedures (disinfection)
- Hyperemization in case of capillary puncture

Anticoagulation

- Recommended anticoagulant: heparin
- Recommended dosage: 1000 IU/mL
- Ensure even mixture of sample and heparin in syringes
- Use glass or plastic syringes with even heparin coating (e.g. AVL glass capillaries)
- AVL Microsampler meets all requirements

Arterial Blood Sampling

Syringe Sampling

- Preferably use artery with collateral supply
- Small needle lumen reduces arterial trauma
- Fill dead space of syringe with heparin solution (1000 IU/mL)
- Avoid strong suctioning of sample
- Compress puncture site

Microsampler Sampling

- Use AVL Microsampler
- Palpation of artery
- Introduce needle almost vertically with slight incline towards proximal
- Observe lightly pulsating blood flow
- Pull needle back after complete filling
- Compress puncture site

Capillary Sampling

- Wipe off first drops of blood
- Collect blood close to puncture site
- Work fast to avoid air contact
- Apply bandage to puncture site

Storage and Transport of Samples

- Analyze blood gas samples as soon as possible
- Close sample container for transport, avoid air contact
- Cool syringe samples in ice (sample cools faster in thin syringes)
- Samples taken with glass capillaries can be stored at room temperature for a minimum of one hour without significant value changes.
- Certain analyzers may require warming of the sample before input into the analyzer.

Sample Analysis

 For a description of this procedure, please refer to the respective operator's manuals.